The effect of yoga on women with secondary arm lymphoedema from breast cancer treatment. A pilot trial.

by

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Declaration

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The following two publications have been peer-reviewed.

Publication one: Trial Protocol

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Also, the following poster, two plenary and two keynote oral presentations and two workshops, each with published abstracts, have been peer-reviewed.

Poster: Exercise and Sports Science Australia (ESSA) conference, Gold Coast, April 19-21, 2012 www.essa.org.au/conference2012

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Tony Barnett; Andrew Williams; Neil Piller; Maarten Immink; Denis Visentin: contributed to the formalisation, refinement and final draft of the published papers.

Andrew Williams: contributed to the formalisation and final draft of the poster and defended it at the ESSA conference, Gold Coast, April 2012.

I declare that the above-stated "proportion of work undertaken" for each of the above published peer-reviewed manuscripts contributed to this thesis:

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ABSTRACT

This thesis reports the effect of an integrated yoga practice on women diagnosed with secondary arm lymphoedema from breast cancer treatment (n=28). The study design was a blinded Randomised Controlled Trial in Hobart and Launceston (Tasmania) from February to May 2011.

The literature suggests that at least 20% of women treated for breast cancer will develop secondary arm lymphoedema, leading to a reduction in upper body function and quality of life. There is evidence to support the use of exercise, based on breathing, gentle movement and relaxation, with progression in the level and adequate warm-up and cool-down, in the management of this chronic and often debilitating condition. An integrated yoga practice, based on these principles, has been investigated for people with lower limb lymphoedema from filariasis and for women during and after breast cancer treatment, with positive outcomes. This suggests that a similar intervention may be helpful for women with breast cancer-related lymphoedema (BCRL).

As no published research was located on the topic, this study was undertaken to evaluate the impact yoga may have on women with BCRL. As such, it provided novel findings to support further research, as well as the development of guidelines for use by yoga teachers.

The intervention was eight weekly sessions of a teacher-led 90-minute yoga class and a daily home-practice using a DVD (42 minutes). The control group continued with current care. Randomisation occurred after the baseline measurement. Other measurements were at weeks 4 and 8 with a four-week follow-up measurement at week 12. Primary objectives of the study were to determine the effect of yoga on lymphoedema in terms of lymphoedema level, tissue density, the degree of sensations, pain and fatigue and their limiting effects on daily activity and quality of life. Secondary objectives were to determine the effect of yoga on upper body impairment in terms of range of motion of the shoulder and spine and strength of grip, shoulder and the muscles affected by surgery (pectoralis major, pectoralis minor and serratus anterior). Amount of physical activity, demographic and medical information were also obtained from participants. Through interview subjective information was sought from the intervention participants about their perception of the effects of yoga and the effectiveness of the home-practice DVD.

Data was collected through bioimpedance spectroscopy, arm and hand circumferential readings, visual analogue scales, tonometry, goniometry, dynamometry, optoelectronics and questionnaires (including the LYMQOL quality of life measure and the International Physical Activity Questionnaire - short form).

Descriptive data was analysed by SPSS, version 19. Primary and secondary outcomes were analysed by STATA, version 12. The level of significance was set at $p<0.05$. Data from the interviews was analysed using an iterative-thematic approach.

Results showed that lymphoedema was not exacerbated over the 8-week study period and arm volume of lymphoedema improved significantly ($p=0.029$) for the intervention group. In comparison to the control group, the intervention group demonstrated reductions in tissue density of the affected upper arm ($p=0.050$), symptoms ($p=0.038$), the degree to which pain limited activity (0.035) and also improvement in pelvic stability for lateral flexion of the spine ($p=0.023$). Whilst the control group improved in comparison to the intervention group in range of motion for the non-affected arm in flexion ($p=0.011$) and abduction ($p=0.049$), the intervention group demonstrated improved symmetry in these actions. Most of these improvements were not maintained at week 12. Moreover, in comparison to the control group, the intervention group increased in arm volume of lymphoedema ($p=0.032$) and in decreased internal rotation for the affected arm ($p=0.001$) at week 12.

During the interviews, participants reported improvements in many aspects of physical function and quality of life which were not measured by instruments. Examples included increased physical and mental awareness, calmness, wellbeing, time for self and improved relationships and various physical functions such as better digestion and elimination, improved posture and ease of movement. In addition, there was positive feedback about the conduct of the class, benefits of group interaction and the effectiveness of the DVD. Nine of the 15 women reflected on a personal change that had occurred in them during the yoga intervention. Participants also talked about the stress of their breast cancer experience, irrespective of how long ago they had been diagnosed. Subjective comments were supported by objective scores for many outcomes such as level of lymphoedema, tissue density, quality of life, shoulder and spinal range of motion.

The findings provide a basis for the recommendation of yoga as a complementary therapy for women with BCRL, and for the development of guidelines for yoga teachers. However, further research is warranted to better elucidate the benefits of yoga for this population.

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It is with gratitude that I acknowledge the financial contribution towards this study by the Swan Research Institute (SRI) and the Faculty of Health Sciences, UTAS.

The greatest practice of yoga is known as Seva Yoga, a term which describes actions that are carried out with compassion and integrity in order to assist, whenever help is needed. The practice is stronger when such actions are done collectively. The realisation of the research on which this thesis is based has been a product of Seva Yoga, through the many people who have so generously and selflessly contributed to its fruition.

In the mid-90s, my life changed in a then unknown way as women with breast cancer and BCRL began to attend my yoga classes on the Northern Beaches of Sydney. These women, and the countless more I have met and taught yoga since then, have been my inspiration without whom this research would not have eventuated. In particular, I would like to acknowledge Sue Forsyth, the late Janet Hensley, and Vicki Besso, who continued to believe in my ability to return to study.

In choosing to base my research on the Satyananda® Yoga tradition, I was encouraged by Mudita Mariette Maclurcan, and inspired by the late Swami Satyasankalpa Saraswati, whose courage and belief in the practices of yoga for women with breast cancer and BCRL, sustained me at times during the difficulties that research inevitably brings. This style of yoga was ably and beautifully demonstrated in the DVD that we made for this trial by yoginis Lynn Englefield and Denise Las.

Professor David McNeil paved the way for my study in Rural Health at UTAS and continued to add support to the project throughout its entirety.

When talking to women with BCRL, who often feel neglected and forgotten, I tell them that each of my supervisors responded enthusiastically to my request for their supervision, and has continued to support my belief in the need for this study. To Associate Professor Tony Barnett, Dr Andrew Williams, Professor Neil Piller, Dr Maarten Immink and Dr Denis Visentin I am indebted for the unique knowledge base and academic and practical suggestions that each offered. Beyond their encouragement and academic leadership, I would like to acknowledge the compassionate help offered when needed by my Tasmanian supervisors Associate Professor Tony Barnett and Dr Andrew Williams. The very approachable UTAS library staff, in particular Katrina Dewis for research skills and Steve Street for technical assistance, provided valuable support.

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This study depended on many measures to answer the research questions raised by my personal observations as a yoga teacher working with this group of women. The research would not have been possible without the expertise offered by Chris Dale and Marlene Kalis in lymphoedema measurements, and their volunteer helpers – Sue Pickard, Jenny Markovitch, Jill Clennett and Anel Loubser. The final-year Human Life Sciences students Belinda Mann, Kara Spaulding, Lara Matuszek and Megan Reid brought an added dimension to the measurements, not only in their precise measuring techniques but also in the heartfelt way they communicated with each woman. The team was completed by the enthusiastic help offered by Christine Lambrechts and Michele Smith. The warmth, sincerity and professionalism of this unique team of women contributed to the highly positive feedback that was received from the women participating in the trial.

Community venues for the yoga and measurements were donated by the Hobart Women's Health Centre, North Hobart, the Launceston Community Health Centre, Kings Meadows and the Sports Laboratory, Newnham Campus, UTAS, Launceston. Equipment was provided by Flinders University and UTAS.

Local shopkeepers donated food for the measurement sessions, which added further to the warm atmosphere of these sessions. My thanks to Bakers Delight, Newtown and Kings Meadows; Woolworths and Go Vita Health Food Store, Sandy Bay; and Good Food Organic Store, Kings Meadows.

However, this study would not have been possible without the dedicated and unwavering contribution from the women of Hobart and Launceston who volunteered for the trial. These women braved floods, frosts, snow and cold to attend the yoga intervention and measurements, in spite of some severe personal trauma. To each of you I give my heartfelt thanks and promise that you are far from forgotten.

Finally, I offer my humblest and sincerest thanks to Erik Donnachie, not only for his expertise in making the DVD, but whose continued love, support, encouragement, belief in the project and logistic assistance, meant that I could not possibly give up the commitment to my belief in the necessity for this long-awaited piece of research.

In loving memory of Yvonne Nichols.

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ABBREVIATIONS

Abduct	Abduction
Aff	Affected
b-8	Period of measurement from baseline to week 8
8b-12	Period of measurement from week 8 to week 12
BCRL	Breast Cancer Related Lymphoedema
BIS	Bioimpedance Spectroscopy
BMI	Body Mass Index (kg/m^2)
CAM	Complementary and Alternative Medicine
CLT	Complex Lymphoedema Therapy
Con	Control group
Ext	Extension
Ext rot	External rotation
Flex	Flexion
Gp	Group
IMLD	Indian Manual Lymphatic Drainage
Int	Intervention group
Int rot	Internal rotation
IPAQ	International Physical Activity Questionnaire
LACR	Left acromion process
L-dex	Lymphoedema index, to measure unilateral lymphoedema
LPSI	Left Posterior Superior Iliac Spine
Lymph	Lymphoedema
LYMQOL	A validated quality of life questionnaire for people with lymphoedema
$MET.min^{-1}$	Metabolic rate at rest. Unit of measure to define intensity of exercise.
MLD	Manual Lymphatic Drainage
MRI	Magnetic Resonance Imaging
Nonaff	Non-affected
PAL	Physical Activity and Lymphoedema Trial

Pec maj	Pectoralis major
Pec min	Pectoralis minor
QOL	Quality of Life
RACR	Right acromion process
RCT	Randomised Controlled Trial
ROM	Range of Motion
RPSI	Right Posterior Superior Iliac Spine
Sa	Serratus Anterior
Sep	Separate
Ton	Tonometry
Tr	Thoracic rotation
VAS	Visual Analogue Scale

GLOSSARY

Acromion	The lateral highest point of the scapula, used as a landmark for shoulder measurement.
Adipose tissue	Fatty tissue.
Arterial system	The transport of oxygenated blood in the circulatory system away from the heart.
Axillary nodes	The lymph nodes located in the area of the armpit.
Capillaries	The smallest vessels of the circulatory system.
Cervical spine	The top seven vertebrae of the spine.
Collateral pathway	A new pathway for the flow of lymph after damage to the lymph system.
Cording	Tender vertical cords in the armpit after removal of lymph nodes, that may extend down the arm, and will eventually disappear.
Cubital fossa	The area in the front of the elbow crease used as a landmark for measurement.
Extra-cellular fluid	The body fluid outside the cells.
Distal	Far away from the centre of the body.
Fibrosis	Excess fibrous tissue formed by scar tissue and lymphoedema causing a build-up of proteins in the tissue, which becomes hard and oxygen-deprived.
Filariasis	A parasitic disease spread by contaminated mosquitoes, which attacks the lymphatic system leading to lymphoedema, prevalent in Asia and Africa.
Frontal plane	The vertical plane through the human body, dividing the front and back.
Inguinal nodes	The lymph nodes located in the crease of the groin.
Interstitium	The space between cells.
Isometric exercise	Exercise based on sustained muscle contraction held over a period of time.
Isotonic exercise	Exercise based on repeated contraction of muscles, as opposed to holding a muscle contraction.
Kinematic	The movement chain of the body, whereby one section moves to create movement in the next section.
Lumbar spine	The lowest five vertebrae of the spine.
Lymphangiogenesis	The growth of new lymph vessels.
Lymphoedema	The disruption to the lymph transport system leading to swelling in the area of obstruction.

Lymphoscintigraphy	A method to check the lymph system by following the flow of an injected radioactive substance with a specialised camera and computer system .
Lymph territory	An area in the body that drains the lymphatic system for that part of the body, e.g. the right upper quadrant of the trunk will drain to the right axillary nodes.
Metacarpophalangeal joint	The mid-point of the hand for circumferential measurements.
Posterior superior Iliac spine	The highest point of bone from the posterior iliac spine from which measurements can be made.
Proximal	Close to the centre of the body.
Sagittal plane	The vertical plane through the human body dividing left and right.
Spinal processes	The central protruding bones of the vertebrae on the back.
Subscapular fossa	The hollow at the top of the scapula used as a landmark for measurements.
Tai-chi	A traditional Chinese movement system, originally based on martial arts, used more now for its health benefits.
Thoracic spine	The middle twelve vertebrae of the spine.
Transverse plane	The horizontal plane through the human body dividing the upper and lower at the waist.
Ulnar styloid process	The highest point of bone of the ulnar, on the little finger side of the wrist, used as a landmark for measurement.
Vascular	Relating to the blood vessels of the circulatory system.
Venous system	The transport of de-oxygenated blood in the circulatory system back to the heart.
Watershed	The line between two lymph territories. Lymph can be manually made to cross from one watershed to another.

CHAPTER ONE INTRODUCTION

There is currently no published research into the effect of yoga on women with secondary arm lymphoedema arising from breast cancer treatment (breast cancer-related lymphoedema, BCRL). However, there are significant indications that research is needed.

The benefits of physical activity on BCRL have been shown from well-designed trials using resistance training (Kwan, Cohn, Armer, Stewart, & Cormier, 2011; Schmitz, Ahmed, et al., 2009) and have led to changed guidelines for the adoption of physical activity for women with BCRL (National Lymphedema Network, 2011b). Smaller trials involving yoga-related activity, including gentle movement, breathing and relaxation, have also had beneficial results by improving lymphoedema levels, reducing symptoms and sensations, and improving other physical outcomes (McClure, McClure, Day, & Brufsky, 2010; Moseley, Piller, & Carati, 2005). Holistic treatment has long been recommended due to the multifactorial effects of BCRL on women's lives (Morgan, Franks, & Moffatt, 2005). Yoga is an integrated program which includes practices for the body and mind, and can be used alongside other therapies as part of a holistic treatment. In fact, one such holistic treatment plan, based on traditional and western medicine, including yoga therapy, has reduced lower limb lymphoedema from filariasis (Bose & Aggithaya, 2011; Narahari, Ryan, Mahadevan, Bose, & Prasanna, 2007).

It is proposed that yoga may offer another option for the management of the adverse effects of BCRL, by improving aspects of physical, mental and emotional wellbeing. Recent research has shown that many women with BCRL are already using yoga as a self-management technique (Finnane, Liu, Battistutta, Janda, & Hayes, 2011). So, research is both warranted and essential.

This pilot trial was carried out to determine the effectiveness of an integrated yoga practice as part of women's holistic treatment for BCRL.

1.1 Summary of literature review

Secondary arm lymphoedema from breast cancer treatment is the result of a disruption to the lymphatic system (Rockson, 2001). Modified breast cancer treatment has reduced, but not eliminated, the prevalence of secondary lymphoedema and at least 20% of women continue to be affected (National Breast and Ovarian Cancer Centre, 2008c). Changed treatment methods include modified radical mastectomy, radiation targetted to other areas rather than solely to the axilla, and sentinel node biopsy rather than complete axilla clearance when possible. The number of risk factors presented by the patient including treatment and high BMI (Thomas-MacLean, Miedema, & Tatemichi, 2005), and an individual

predisposition, such as higher filtration rates and genetics (Stanton, Modi, Mellor, Levick, & Mortimer, 2009), all appear to be linked to the occurrence of BCRL.

BCRL causes (1) swelling of the affected arm as a result of the collection of protein-rich fluid in the interstitium and (2) changes to the adipose tissue that can make the arm more vulnerable to infections such as cellulitis (Warren, Brorson, Borund, & Slavin, 2007). BCRL is incurable and can affect women physically, emotionally and socially (Keeley, et al., 2010). Physical upper body impairment (Hayes, Janda, Cornish, Battistutta, & Newman, 2008a) and reduction in quality of life (QOL) (Beaulac, McNair, Scott, LaMorte, & Kavanah, 2002; Pyszel, Malyszczak, Pyszel, Andrzejak, & Szuba, 2006) can be greater in women with BCRL than in those treated for breast cancer without lymphoedema. Fibrous tissue caused by surgery, radiation and lymphoedema can worsen these adverse effects (Brennan, 1992), as can pain (Dawes, Meterissian, Goldberg, & Mayo, 2008), fatigue (Armer & Porock, 2002), and the actual swelling of the arm (Morgan, et al., 2005). Affected women also experience a number of sensations that can cause discomfort, such as heaviness, tingling, aching and heat (Morgan, et al., 2005). In addition to the swelling and tissue changes, altered biomechanics of the thoracic spine, scapula and humerus can cause further upper body impairment, creating postural problems and a lack of symmetry between the affected and non-affected sides of the body (Balzarini, et al., 2006; Rostkowska, Bak, & Samborski, 2006; Shamley, Srinanaganathan, Oskrochi, Lascurain-Aguirrebena, & Sugden, 2009). Daily activity can be compromised and activities such as driving, carrying a heavy bag and repetitive movements, can exacerbate lymphoedema (Norman, et al., 2009). Overall QOL can be compromised in women with BCRL as a result of a lowered body image, a fear of lymphoedema becoming worse and a sense of marginalisation and reduced self-effectiveness (Johansson, et al., 2003; Ridner, 2009; Ridner, Bonner, Deng, & Sinclair, 2012; Ridner, Dietrich, & Kidd, 2011).

BCRL is a lifelong condition that requires management by complex lymphoedema therapy (CLT), as well as daily self-management, to prevent the condition worsening or infection developing. CLT involves manual lymphatic drainage (MLD) by trained therapists, compression bandaging, remedial exercises and education in self-management techniques. It is recommended that, in addition to CLT as required, women with BCRL be offered holistic treatment options to help maintain their motivation in keeping lymphoedema under control (Lymphoedema Framework, 2006).

Exercise, as part of holistic treatment, can improve women's physical health and QOL (Fitzgerald, 2007; Turner, Hayes, & Reul-Hirche, 2004). There is a growing amount of evidence across a broad sphere of exercise modalities showing that, with supervised and progressive exercise, women with BCRL can exercise safely under controlled conditions, which include

adequate rests and warm-up and cool-down periods (Kwan, et al., 2011; Schmitz, 2009; Schmitz, Troxel, et al., 2009). Exercise guidelines for women with BCRL reflect these research findings (National Lymphedema Network, 2011b).

Evidence for the benefits of exercise comes from post-operative studies, as well as from studies on women with, or at risk of, secondary lymphoedema. Post-operative progressive and supervised exercise for shoulder range of motion (ROM) (Box, Reul-Hirche, Bullock-Saxton, & Furnival, 2002a) and strength (Sagen, Karesen, & Risberg, 2009), assessed for two years, did not cause or exacerbate lymphoedema and reduced arm impairment. Post-treatment exercise of various modalities for women with or at risk of lymphoedema has also resulted in lymphoedema decreasing or staying the same, as well as in improvements in QOL and other physical parameters (Kwan, et al., 2011; Moseley & Piller, 2008). The largest exercise Randomised Controlled Trial (RCT) to date, based on a year-long resistance training intervention on women with BCRL, resulted in a reduction in self-report of symptoms, fewer exacerbations from lymphoedema and no increase in swelling, in addition to an improvement in strength (Schmitz, Ahmed, et al., 2009) and body image (Speck, et al., 2010).

Another option for improving BCRL may involve breathing, various forms of gentle exercise and relaxation. The basis of this option centres on the way lymph fluid moves physiologically. Lymph moves through the body by the action of muscles, pressure changes from slow diaphragmatic breathing, the arterial pulse and an intrinsic lymph pump (Lane, Worsley, & McKenzie, 2005). Lymph moves very slowly and can be redirected to other pathways. Diaphragmatic breathing enables the lymph to re-enter the venous system at the lymphatic ducts, thus enabling lymph to flow more easily (Vaqas & Ryan, 2003). An RCT investigating the effect of *tai-chi* and breathing found the intervention reduced the self-report of symptoms and fibrous tissue at the chest (Moseley, et al., 2005). Another RCT based on gentle exercises, breathing and relaxation reported increased shoulder ROM and improved QOL (McClure, et al., 2010). In both these trials, the volume of lymphoedema decreased.

Remedial exercise, based on MLD principles of clearing proximal to distal, with slow breathing and relaxation, has been effective in maintaining or slightly lowering levels of lymphoedema in individual self-management (Casley-Smith, 1999), in physiotherapy groups (Bracha & Tamar, 2010) and in group water-based exercise (Tidhar & Katz-Leurer, 2010). Principles of lymphatic clearance by slow and progressive movement, breathing practices, leg elevation and relaxation are the basis of the yoga therapy for lower limb lymphoedema from filariasis (Narahari, Ryan, Bose, Prasanna, & Aggithaya, 2011; Ryan & Narahari, 2012). Although these studies vary in sample size, design method and statistical analysis, the findings are positive and indicate that yoga may also have positive outcomes.

Yoga, with its slow breathing, progressive exercise, meditation and relaxation, is an integrated system that balances the body, energy, mind and emotions in a holistic way to enable each individual to function to their potential, whatever their situation (Iyengar, 2001). Its practices have developed over thousands of years from many traditions. Yoga has been researched in ill and healthy populations as an integrated practice, and also for its different practices (Evans, Sternlieb, Tsao, & Zeltzer, 2009; Raub, 2002). It offers a biopsychosocial model of health (Evans, et al., 2009).

Yoga, as an integrated practice, has been researched for its benefits for women during and after their breast cancer treatment and has resulted in improved QOL (Chandwani, et al., 2010), mood and acceptance (Carlson, Speca, Patel, & Goodey, 2003; Carson, et al., 2007; Vadiraja, Raghavendra, et al., 2009), immunity (Carlson, Speca, Faris, & Patel, 2007; Rao, et al., 2008) and reduced fatigue (Bower, Garet, & Sternlieb, 2011), joint pain (Galantino, et al., 2011), anxiety and depression (Rao, et al., 2009). Those with arm impairment have reported improvement in wellbeing (Thomas-MacLean, et al., 2010).

Yoga interventions in other populations have resulted in improved thoracic spine mobility (Greendale, Huang, Karlamangla, Seeger, & Crawford, 2009), shoulder strength (DeAvilla, 2007) and core strength (Omkar, Vishwas, & Tech, 2009). The physical postures are based on postural alignment, engaging the stabilising muscles of the joints and core, and initiating movement through a kinematic chain of muscle involvement, with mental awareness (Borg-Olivier & Machliss, 2004; Coulter, 2001; Myers, 2001). This may also improve impaired posture and the biomechanics of thoracic-scapulohumeral rhythm. Studies on yoga methods of breathing (Kjellgren, Bood, Axelsson, Norlander, & Saatcioglu, 2007; Telles, Nagarathna, & Nagendra, 1994), meditation (Arias, Steinberg, Banga, & Trestman, 2006) and relaxation (Telles, Reddy, & Nagendra, 2000) have shown improved mood and reduced stress.

All these outcomes may be transferrable to women with BCRL.

1.2 Aim

The aim of this study was to evaluate the effect of an eight-week integrated yoga intervention on women with stage one BCRL.

1.2.1 Research questions

For women with BCRL stage one:

1. Does an integrated yoga practice:

   i Reduce the levels of lymphoedema, tissue density (fibrosis) associated with lymphoedema, sensations, pain and fatigue, and the degree to which sensations, pain and fatigue limit daily activity?

ii Have an effect on QOL?

iii Have an effect on upper body function, including ROM of the shoulder and spine, grip strength, and strength of the shoulder and the three separate muscles that can be affected by treatment (i.e. serratus anterior, pectoralis major and pectoralis minor)?

iv Have other subjective effects on women?

2. Is a yoga class delivered by DVD an effective tool for the home-practice of an integrated yoga intervention?

1.3 Research design and outcome variables.

The study was a randomised controlled pilot trial in Tasmania, Australia, with the measuring staff blinded to group distribution. Measurements were made at baseline (pre-randomisation), week 4, week 8 and one month after the intervention at week 12. The yoga intervention involved participation in a weekly yoga session (90 minutes) and a daily home-practice based on a DVD (42 minutes) specially made for this trial. The control group continued with best current care. Demographic and medical information was collected by a questionnaire at baseline.

The primary objectives and measuring tools were:

1. Lymphoedema status by the level of extra-cellular fluid measured by bioimpedance spectroscopy (BIS) and calculation of arm and hand volume of lymphoedema by circumferential readings;
2. Tissue density at the forearm, upper arm, chest and upper back by tonometer;
3. Degree of sensations, pain, fatigue and their limiting effects by a Visual Analogue Scale (VAS);
4. QOL by a specific tool for lymphoedema (LYMQOL).

The secondary objectives and measuring tools were:

1. ROM of the shoulder by goniometer;
2. ROM of the spine in a optional sub-group by optoelectronic equipment;
3. Strength of the shoulder and separate muscles by hand-held dynamometer;
4. Grip strength by grip dynamometer;
5. Weekly activity by the International Physical Activity Questionnaire (IPAQ) short form;
6. Daily activity by a VAS scale.

Subjective information on the effects of the yoga and the effectiveness of the DVD was collected by a 20-minute interview at the completion of the yoga intervention.

1.4 Limitations

Available funds for the research were limited, so that:

1. Pre-testing of women's levels of lymphoedema did not occur, but to counteract this, referral to the trial had to be by a qualified lymphoedema therapist;
2. The trial was dependent on the donation of the venue and most of the equipment. Therefore, only a small practice for assessors could take place with four women with BCRL. Consequently, some of the problems with equipment did not emerge until the baseline testing, notably with the hand-held dynamometer and the visibility of the lumbar translucent markers on obese women;
3. Limited advertising existed to locate participants, so the sample size was small.

In addition:

Return to unrelated group exercise classes by some members of the control group coincided with the commencement of the yoga intervention.

1.5 Strengths

The pilot trial had many strengths including:

1. Being a randomised controlled trial with assessors blinded to group allocation and previous testing;
2. The high level of expertise and consistency of staff;
3. Good protocols for recruitment of women, randomisation, measurement sessions, yoga intervention, data storage and data analysis;
4. Good statistical analysis of quantitative data using STATA software, and sound method of analysis of qualitative data by two researchers developing themes and sub-themes independently.

1.6 Organisation of the thesis

The thesis is organised as follows:

Chapter 2 - Literature review: provides an analysis of the background of breast cancer, lymphoedema, BCRL and yoga research, which was required for the development of the study rationale and design.

Chapter 3 – Methods: describes the details of the trial design, methods and protocol, as well as the details of the yoga intervention.

Chapter 4 – Results 1: presents the demographic and medical characteristics of the sample, followed by the quantitative results of the primary and secondary objectives, after analysis by STATA software. It concludes with some examples of the association between subjective comments from the interviews and individual objective scores.

Chapter 5 – Results 2: presents the qualitative results of the interviews, organised into the themes and sub-themes that emerged from an iterative-thematic analysis, including examples of women's personal reflections.

Chapter 6 – Discussion: presents the discussion of the results from chapters 4 and 5 in the context of other research, and details the strengths and limitations of the current trial.

Chapter 7 – Conclusion: presents the conclusion, with recommendations arising from the trial.

1.7 Significance of the study

Currently, there is no published research into the effect of yoga on women with BCRL, although some women with BCRL are already attending yoga classes. The findings of the current trial will provide essential information about the effectiveness of yoga as a complementary therapy in the treatment of BCRL. It will also inform the methods for future trials and will contribute to the development of safe and appropriate guidelines for yoga teachers when working with women with BCRL.

CHAPTER TWO LITERATURE REVIEW

This chapter will review the literature that has informed the need for and context of the current trial as well as the development of the yoga intervention and methodology. The key areas that provide this core background information include breast cancer, its treatment and effects; lymphoedema from breast cancer, its diagnosis, treatment and effects; exercise for women with BCRL; Complementary and Alternative Medicine (CAM); yoga as a holistic system and yoga research that may have transferrable outcomes for women with BCRL.

A search for relevant research publications was undertaken using CINAHL, Cochrane database, Embase, Pubmed, Pedro, Scopus and Web of Knowledge and the search engine Summon. A manual and key word search of the contents of the *Journal of Lymphoedema* and *Lymphology* (2005-2011) and the research bibliography of the International Association of Yoga Therapists (IAYT) was also undertaken. Search terms, used in various combinations, included yoga, lymphoedema, CAM, relaxation, breathing, breast cancer, exercise, thoracic spine, core stability.

2.1 Breast Cancer

2.1.1 Breast cancer - Incidence

Based on Australian records between 2002-2006, breast cancer is the most commonly diagnosed cancer in Australian women with a projected increase of 22% by 2015. One in eleven women will be diagnosed with breast cancer by age 75, and one in nine women by age 85. Breast cancer has an 88% five-year survival rate. These statistics are similar throughout the western world (Australian Institute of Health and Welfare & National Breast and Ovarian Cancer Centre, 2009).

The rate has increased substantially due to Breast Screen's successful targetting of women aged 40-69, the age group with the highest incidence of breast cancer. Reported rates are lower in populations where screening is not accessed, such as women from lower socioeconomic groups and indigenous women, though methods to better target these women are being implemented (National Breast and Ovarian Cancer Centre, 2010).

2.1.2 Breast cancer - Treatment and its effects

Breast cancer can be primary or secondary. The aim of treatment is to eliminate the cancer in primary breast cancer and in secondary breast cancer to prevent relieve symptoms, prolong life and improve quality of life. Depending on its stage (how far it has spread in the breast and lymph nodes or to other parts of the body) and grade (range:

1=slow growing to 3=fast growing), treatment consists of a combination of surgery, chemotherapy, radiotherapy and hormonal therapy (National Breast and Ovarian Cancer Centre, 2008b).

Traditional surgical treatment had severe effects on many women, including the development of secondary lymphoedema and upper body impairment. Consequently, surgery has changed from complete radical mastectomy, removal of large numbers of lymph nodes and axilla radiation to less aggressive surgical and radiological procedures (National Breast and Ovarian Cancer Centre, 2008c). Current surgery is either modified mastectomy, which involves less trauma to the muscles of the serratus anterior, pectoralis major and pectoralis minor by removing the fascia rather than the muscle (Johansson, Tibe, Weibull, & Newton, 2005; Lauridsen, Overgaard, Overgaard, Hessov, & Cristiansen, 2008), or breast-conserving surgery, which removes breast tissue in a procedure known as lumpectomy, also called wide local incision or partial mastectomy (National Breast and Ovarian Cancer Centre, 2008b). Sentinel node biopsy is increasingly offered to women as an alternative to axillary node dissection. Sentinel node biopsy involves tracking an injected radioactive isotope to the sentinel lymph nodes, which are thought to be the first nodes to which the cancer (and the dyed isotope) will spread, and removing those nodes. After inspection, if the sentinel nodes are cancerous, then axillary dissection is performed. Axillary dissection involves removal of lymph nodes by surgery, and will also affect the pectoral muscles (Harris, Campbell, & McNeely, 2004). Radiation is now more often targetted to specific areas such as the neck or chest than to the axilla (National Breast and Ovarian Cancer Centre, 2008b).

2.1.3 Breast cancer – Effects of treatment on the upper body

In spite of changes to surgery and radiation, there are still many sequelae of breast cancer treatment which cause upper body problems and impaired function, such as pain, numbness, reduced ROM and strength of the shoulder, and lymphoedema (Helms, Kuhn, Moser, Remmel, & Kreienberg, 2009), as well as pectoral tightness and rotator cuff problems (Yang, et al., 2010). These adverse effects lead to altered thoracic-scapulohumeral functioning (Crosbie, et al., 2010; Malicka, Barczyk, Hanuszkiewicz, Skolimowska, & Wozniewski, 2010; Merchant, Chapman, Kilbreath, Refshauge, & Krupa, 2008; Shamley, et al., 2009; Shamley, et al., 2007) and changed posture (Malicka, Barczyk, et al., 2010; Shamley, et al., 2007).

Different treatments affect shoulder and arm function to varying degrees. The most severe effects are from modified mastectomy (Harrington, et al., 2011; Lauridsen, et al., 2008) when combined with radiation (Gosselink, Rouffaer, Vanhelden, Troosters, & Christiaens, 2003; Nesvold, Dahl, Lokkevik, Marit Mengshoel, & Fossa, 2008), and axillary node dissection (Nesvold, et al., 2008). However, radiation other than to the axilla has less impact (Hayes,

Battistutta, & Newman, 2005; Lee, Kilbreath, Refshauge, Herbert, & Beith, 2008). Studies comparing the effect of sentinel node biopsy and axillary dissection have found that arm morbidity is significantly higher in those having axillary node dissection irrespective of the type of breast surgery (Hack, Cohen, Katz, Robson, & Goss, 1999; Helms, et al., 2009; Langer, et al., 2007; Leidenius, Leivonen, Vironen, & Von Smitten, 2005).

Moreover, surgery and radiotherapy can lead to vascular changes and the development of fibrous tissue in the chest and upper back causing tightness and pain, which further impair chest and shoulder movement (Brennan, 1998; Lauridsen, et al., 2008). Pectoral tightness from mastectomy and radiation (place of radiation not disclosed) was associated with upper limb problems, such as lymphoedema and rotator cuff dysfunction, 12 months after surgery in a longitudinal study of 191 women (Yang, et al., 2010). Changes to the tissue of the pectoral muscles from radiation can become permanent if movement is not initiated early in recovery (Johansson, Ingvar, Albertsson, & Ekdahl, 2001).

Other muscles can also be affected by breast cancer treatment. In one study using myography and MRI, the muscles affected by surgery were scanned in arm elevation (Shamley, et al., 2007). The serratus anterior, pectoralis major and pectoralis minor were reduced in size in women who had shoulder impairment and pain up to six years after surgery. The reduced muscle size was worse in women who had full or partial mastectomy and radiotherapy to the trunk. The study also showed weakening of the muscles of the upper trapezius and rhomboids, an effect exacerbated in women who had axilla radiotherapy, axillary node dissection and mastectomy. Another study, using muscle testing for arm elevation (Merchant, et al., 2008), also found weakness in the protractors (serratus anterior, pectoralis major and pectoralis minor) and retractors (rhomboids and trapezius) of the scapula, but no correlation was made with the type of treatment

As these affected muscles stabilise the scapula in arm movement, scapulothoracic rhythm is altered (Crosbie, Kilbreath, Hollmann, & York, 2008; Shamley, et al., 2009) and so the thoracic (Crosbie, et al., 2010) and cervical spine (Jahr, Schoppe, & Reisshauer, 2008) are also affected after surgery. Changed scapulothoracic rhythm leads to altered scapulohumeral rhythm, which may account for the reduction in ROM and strength of the shoulder reported after breast cancer treatment.

This altered rhythm may further affect posture. In one study, faulty posture was reported in 82% of women after breast cancer treatment compared to 35% of healthy, age-matched women; 84% of the treated women had radical mastectomy (Malicka, Hanuszkiewicz, Stefanska, Barczyk, & Wozniewski, 2010). The treated women had increased thoracic kyphosis when compared to the healthy women. However, another trial that tested posture in women

after breast cancer treatment found only 30% of the women had increased thoracic kyphosis, 30% had increased lumbar lordosis and 40% had a balanced body posture (Hanuszkiewicz, Malicka, Stefanska, Barczyk, & Wozniewski, 2011). The researchers in this latter study noted that most of the women tested were taking part in exercise classes, which may have reduced the incidence of faulty posture when compared to other studies. In another study, dropped shoulder with straightened thoracic spine, and thoracic kyphosis were reported as two opposite postural types in women after breast cancer treatment which involved any combination of mastectomy, axillary dissection and radiotherapy, (Shamley, et al., 2007).

Functionally, lack of coordination between the thoracic spine, scapula and humerus can lead to difficulty in lowering the affected arm with a weight (Shamley, et al., 2007), weight-bearing overhead (Merchant, et al., 2008), pushing actions (Thomas-Maclean, et al., 2008) and playing sport (Harrington, et al., 2011; Leidenius, et al., 2005). As the serratus anterior and the rhomboids are served by motor nerves which will not give the pain response that sensory nerves give, women do not feel pain when the muscle is used incorrectly and so correction of the faulty use of these muscles is further impeded (Kendall, Kendall-McCreary, Provance, Rodgers, & Romani, 2005, p. 338). However, when pain is felt from other causes such as surgery, fibrosis and lymphoedema, the degree of pain can reduce upper body functioning (Karki, Simonen, Malkia, & Selfe, 2005; Sagen, Karesen, & Risberg, 2009; Thomas-Maclean, et al., 2008).

The most burdensome tasks for women after breast cancer treatment, collated from a questionnaire sent to 619 women, were those requiring whole body strength, upper body strength such as carrying, upper body flexibility or those actions involving the hand or weighted flexion of the arm (Hayes, Battistutta, Parker, Hirst, & Newman, 2005). The women with the highest task burden were those with lymphoedema or poor physical fitness. Half of the women had been treated for breast cancer in the previous three years and the remainder had survived for up to 45 years, showing the length of time that difficulties can be experienced.

This prolonged time factor for shoulder impairment was also reported in a large study of 509 women, by 75% of women older than 60 years, five to nine years post-surgery, though the type of treatment was not disclosed (Mishel, et al., 2005). However, in other studies, prolonged impairment was more severe in women who had axillary node clearance rather than sentinel node biopsy (Helms, et al., 2009) and also severe for those who had axillary node clearance and radiation (Harris, et al., 2004; Lauridsen, et al., 2008).

Women who have pre-existing shoulder disorders will have greater impairment post-surgery (Box, Reul-Hirche, Bullock-Saxton, & Furnival, 2002b; Leidenius, et al., 2005). The effect of age is debated. Some studies report older women have worse arm problems (Karki, et al., 2005) and experience more pain than younger women (Hack, et al., 1999), whereas other studies have found that age does not affect impairment (Hayes, Battistutta, Parker, et al., 2005; Lauridsen, et al., 2008).

The only study to date that has compared shoulder function in women six months after breast cancer treatment with healthy, age- and BMI-matched women found significantly lower scores for ROM, strength and function in the women treated for breast cancer (Harrington, et al., 2011).

Although the results vary across studies, it is clear that women experience effects from breast cancer treatment that cause arm, upper body and perhaps whole body impairment in everyday functional activities. More aggressive treatments, such as modified mastectomy, axilla clearance and radiation, result in greater impairment and effects can be experienced for years after surgery. More aggressive treatments are also risk factors for lymphoedema, so women with BCRL may also have these physical effects, which need to be considered in any physical therapy.

2.1.4 Breast cancer – Other effects

Breast cancer treatment has many other adverse effects which can affect women physically and mentally. Early post-surgical problems are the formation of seroma (a pocket of fluid) and infection. Cording as a result of surgery and axilla clearance also occurs. Fatigue, neuropathy and lowered immunity are associated with both radiotherapy and chemotherapy, along with specific effects such as nausea from chemotherapy and burning from radiotherapy (Caban & Yadav, 2008).

Various medications are used to prevent the production of cancer cells, depending on the type of cancer. Hormone-receptive positive treatments, such as Tamoxifen and aromatase inhibitors, can cause hot flushes, aching joints, loss of balance, mood swings, anxiety and depression (Breast Cancer Network Australia, 2007; National Breast and Ovarian Cancer Centre, 2008b). Effects of targetted therapies such as Herceptin® are unknown but are thought to include heart problems (National Breast and Ovarian Cancer Centre, 2008b).

Breast reconstruction is becoming more common, either at the time of surgery or later. It may involve the insertion of tissue from other muscles such as the abdominals, latissimus dorsi or gluteal muscles or tissue from the other breast, and may lead to weakness in the areas from which the tissue has been taken. Some women choose silicon implants, which can cause tightness across the chest (National Breast and Ovarian Cancer Centre, 2008b). Other

women choose to wear a prosthesis, which, when they are exercising, can be uncomfortable and heavy.

These physical effects need to be understood and considered in any type of exercise intervention. So too do the effects of diagnosis, treatment and related upper body impairment on QOL, which can be adversely affected in many women (Karki, et al., 2005). In one study, women aged less than 50 (n=204) and diagnosed within the previous three and a half years, reported that mastectomy affected body image, chemotherapy affected sexual functioning and hormone therapy created concerns in relation to premature menopause and fertility (Avis, Crawford, & Manuel, 2004). Upper body impairment, particularly pain, was strongly correlated with a lower QOL (Hack, et al., 1999). On the other hand, a five-year study of 204 women who had axillary clearance reported an improved QOL from time of surgery to five years in spite of 36% still experiencing pain (Sagen, Karesen, Sandvik, & Risberg, 2009). A systematic review concluded that QOL remained high after breast cancer surgery and radiation, irrespective of upper limb morbidity (Lee, et al., 2008). Such variation perhaps highlights the variability in the effects of breast cancer treatment.

As women with secondary lymphoedema have also had, or in the case of secondary breast cancer are still having, breast cancer treatment, they have to contend not only with lymphoedema but also with the physical and mental effects from breast cancer treatment, perhaps to varying degrees. In any kind of physical therapy these effects need to be considered.

2.2 Breast cancer-related lymphoedema

2.2.1 The Lymphatic System

The lymphatic system is part of the immune system. It produces lymphocytes and macrophages as part of the body's immune response to unwanted substances (Rockson, 2001). Other functions include the transport of extra-cellular fluid that has diffused into the extra-cellular space (interstitium) from the arterial system, and of other substances back to the venous system. This fluid contains proteins such as bacteria, viruses and other substances like fat, water, cellular debris and foreign material (Szuba & Rockson, 1997). The lymph flows from capillaries, to lymph vessels, to collectors, to nodes at various places in the body, through a one-way valve system (Foldi & Strossenreuther, 2005).

The pumping of lymph is slower than the pumping of blood. Extrinsically at the capillary level, lymph is pumped by movement of the connective tissue until it reaches the larger contractile lymph vessels where intrinsic contractions in the smooth muscle walls continue to move it (Lane, Worsley, et al., 2005). Lymph is also pumped by the pressure changes caused by breathing, the pulse of arteries, positional change and muscle movement (Carati,

Gannon, & Piller, 2009; Harris, et al., 2004; Lane, Worsley, et al., 2005). In the lymph nodes, lymphocytes destroy any bacteria before the fluid re-enters the venous system. Lymph from certain parts of the body flows to specific lymph nodes; for instance, the axilla nodes drain the area of the arm and upper trunk quadrant on the same side. If cancer is in that area of drainage, it will go to the regional lymph nodes (e.g. left breast cancer will go to the left axilla). Watersheds divide the torso into quadrants. In an impaired system, these watersheds can be crossed to create a new (collateral) pathway. For example, lymph can cross the watershed at the chest and flow into the left axilla nodes if the right axilla nodes no longer function; alternatively, it can cross the midline watershed at the waist and be directed to the right inguinal nodes (Foldi & Strossenreuther, 2005).

Lymph returns to the venous system at the left or right lymphatic ducts. The lymph from the right upper quadrant (including half the neck and head, arm and right trunk) drains into the right thoracic duct. The lymph from the whole lower body and left upper quadrant flows into the left thoracic duct (Foldi & Strossenreuther, 2005). The two lymphatic ducts drain into the right and left sub-clavian veins which are behind each clavicle (Lane, Worsley, et al., 2005).

2.2.2 Lymphoedema

In a healthy lymphatic system there is a balance in fluid transport. When a disruption in lymph transport occurs, this balance is interrupted, leading to the swelling known as lymphoedema. The precise aetiology is unknown (Carati, et al., 2009). Lymphoedema has been described as an accumulation of excess protein-rich fluid, water and cell products in the interstitium (International Society of Lymphology, 2009; Warren, et al., 2007), though it also involves an imbalance in the fluid transport in the arterial and venous systems (Carati, et al., 2009; Stanton, et al., 2009). It is incurable and progressively worsens if left untreated (Warren, et al., 2007).

The slowed and oxygen-deprived lymph helps accumulate fatty tissue (Szuba, et al., 2009) which, without treatment, hypertrophies (Rockson, 2006; Warren, et al., 2007), so that the underlying connective tissue turns fibrous, resulting in changes to the consistency of the skin. This fibrous tissue will slow down the flow of lymph, as will scar tissue and fibrous tissue caused by mastectomy and radiation (Pain & Purushotham, 2000).

The affected area becomes a good environment for infections (Warren, et al., 2007). The warm, swollen limb is a good breeding place for bacteria, as circulation has been compromised and the effect of lymphocytes and macrophages that fight bacteria has been slowed. Consequently, the immune system may no longer respond to infection at the cellular level (Mallon, Powell, Mortimer, & Ryan, 1997; Pain & Purushotham, 2000). Cellulitis is one such

infection that can occur. One study found that infections such as cellulitis and lymphangitis were twice as high in women with BCRL (n=180) as in those treated for breast cancer without lymphoedema (n=1697), tested over a two-year period (Shih, et al., 2009).

Lymphoedema can occur as primary or secondary lymphoedema. Primary lymphoedema is a congenital abnormality of the lymphatic system and is beyond the scope of this review. In the western world, secondary lymphoedema is mainly caused by surgery for cancer treatment. In other parts of the world, such as India, secondary lymphoedema can also be caused by filariasis.

2.2.3 Secondary Lymphoedema from breast cancer treatment

The lymph from the arm and the upper body drains through the axillary nodes. Breast cancer treatment causes damage to the axilla drainage by surgery, removal of lymph nodes at the axilla and radiation to the axilla, chest wall, sternum or neck. The result is a disruption to the drainage of the lymph pathways. In some women, collateral pathways open to remove the fluid, whilst in others this does not happen and so the lymph cannot flow away as effectively (Brennan, 1992), leading to the swelling known as secondary lymphoedema (Rockson, 2001). Secondary lymphoedema can be of the arm, breast or chest wall, and may be related to where the radiation has been targetted (Keeley, Lewis, Drury, Narahari, & Gergich, 2007).

High-risk factors for lymphoedema are the surgical interventions of mastectomy, axilla clearance and axilla radiation (Herd-Smith, Russo, Muraca, Del Turco, & Cardona, 2001; National Breast and Ovarian Cancer Centre, 2008a). However, due to the changes in treatment options, there are now more reported variations in treatment risk factors.

A study charted the risk factors for lymphoedema in 287 women, testing for lymphoedema status by BIS every three months from six to 18 months post-surgery (Hayes, et al., 2008a). A full data set was collected for 75% of the participants (n=158). The incidence of lymphoedema 9-18 months post-surgery was 23.4%. Relationships between patient treatment, behavioural characteristics and incidence of lymphoedema were calculated as uncorrected odds ratios and as odds ratios corrected for a range of covariates. Among these women, the highest risk factor was mastectomy, irrespective of the type of lymph node removal. The other high-risk factor was the removal of more than 20 lymph nodes, irrespective of the type of surgery. Risk was increased also for those women who had adverse effects from their treatment. This study found that radiation and BMI were not risk factors. It also reported on the connection between demographic characteristics and lymphoedema, with age over 50 being a significant risk factor, while being younger, having lower socioeconomic standing,

living with another person and being more physically active reduced the odds of lymphoedema.

Two other studies found a significant risk from mastectomy, similar to the abovementioned study by Hayes and colleagues (2008), but reported variation in other risk factors (Ridner & Dietrich, 2008; Swenson, Nissen, Leach, & Post-White, 2009). BMI >25 and radiation to the axilla were significant risks in the study by Swenson and colleagues, along with chemotherapy and the number of positive lymph nodes, rather than the number of lymph nodes removed; however, there was no risk associated with age. Conversely, higher age was a risk in the study by Ridner and Dietrich, as were lower socioeconomic status, high BMI and co-morbid conditions such as arthritis, hypertension and spine and shoulder problems.

A systematic review of 32 longitudinal or cross-sectional studies on the effects of breast cancer treatment which included radiation other than to the axilla (Lee, et al., 2008), found that women having radiation had only slightly higher odds of getting lymphoedema than those who did not, while those having axillary dissection and more than 10 lymph nodes removed were at greater risk. These studies proposed that radiation other than to the axilla may have good prognostic outcomes for women. However, radiation to the breast or chest wall may be causing an increase in breast lymphoedema rather than arm lymphoedema (Keeley, et al., 2007). Studies comparing women who have axilla lymph node dissection with those having sentinel node biopsy reveal a lower incidence in the latter group (Kootstra, et al., 2010; Langer, et al., 2007; Langer, Guenther, Haigh, & Difronzo, 2004; Lee, et al., 2008).

Having a high BMI is reported as a high-risk factor in many studies (Box, et al., 2002a; Edwards, 2000; Mahamaneerat, Shyu, Stewart, & Armer, 2008; Petrek, Senie, Peters, & Rosen, 2001; Ridner, 2005; Sagen, Karesen, & Risberg, 2009). Post-operative swelling and being operated on the dominant arm can also cause a higher incidence (Ridner, 2005). When combined with BMI>30, these factors gave women 60% more chance of developing lymphoedema in another study (Mahamaneerat, et al., 2008).

Factors with little conclusive evidence but which cannot be ruled out because of a high rate of clinical observation include infection after surgery, cording, seroma and having an injection or applying pressure through a blood pressure cuff (Harris, et al., 2001; International Society of Lymphology, 2003; Lymphoedema Framework, 2006). Aeroplane travel, due to the pressure changes within the cabin, has been postulated as a risk factor, with some evidence supporting this notion (Casley-Smith, 1996; Ward, Battersby, & Kilbreath, 2009) and other evidence disputing it (Kilbreath, et al., 2010).

The above discrepancies were reflected in an evidence-based review of research into risk factors for lymphoedema, which concluded that those who will get BCRL cannot be accurately predicted because of the different research methodologies not adjusting for confounding effects (National Breast and Ovarian Cancer Centre, 2008c). While this review supported more conservative treatment, it stated that this alone did not prevent lymphoedema as there was no consistency in the risk factors. Rather, it supported the supposition of other researchers (Thomas-Maclean, et al., 2008) that it is the **number** of risk factors that may lead to the development of lymphoedema. It recommended that larger prospective studies over a long time period be conducted to further clarify likely risk factors.

2.2.4 Predisposition to lymphoedema

Some women may be predisposed to BCRL. Research using lymphoscintigraphy enables study into the actual flow of lymph by injecting a radioactive isotope into a person and watching its uptake in both the affected and non-affected limb by a gamma camera at one time-point (Keeley, 2006). A study comparing the flow of lymph during exercise (arm cranking) and at rest in women with and without BCRL and healthy controls (n=10 in each group), found that the women with BCRL had less flow to the axilla and more lymph activity in the forearm flowing to the dermis (backflow), leading the authors to hypothesise that alternative lymphatic pathways did not regenerate in those women (Lane, Dolan, Worsley, & McKenzie, 2007). Lymph pathways did regenerate in 10 women who were studied following breast cancer surgery with axilla clearance, who did not have lymphoedema (Szuba, et al., 2009). Another study found that lymph pathways were significantly impaired in women with severe lymphoedema (Szuba, Jasinski, Jedrzejuk, Wozniewski, & Andrzejak, 2007). It appears that some women may grow new lymph vessels and thus be less likely to get lymphoedema.

Other studies have postulated that some women may have a predisposition to lymphoedema, perhaps caused by genetics (Newman, et al., 2012), a failure in the lymph pump system, higher filtration rates, or weaker lymph drainage (Modi, et al., 2007; Stanton, et al., 2009). This research may explain why there is such a divergence in the risk factors linked with lymphoedema.

2.2.5 Lymphoedema diagnosis and incidence

Incidence of lymphoedema varies depending on the criteria used for its definition and the method used to diagnose it. This discrepancy is a result of the lack of a standard in measuring and thus diagnosing lymphoedema world-wide. Diagnosis can be based on circumference, volume, amount of extra-cellular fluid, and women's perception of sensations. Circumference can be measured by anthropometrical tape or the insertion of the arm into a perometer; volume calculated from circumference readings, perometry or water displacement; and extra-cellular fluid assessed by BIS.

Each measure is confounded by different definitions of what constitutes lymphoedema; for example, different researchers have based their classification of lymphoedema on circumferential readings >2 cm at any one point (Armer, Stewart, & Shook, 2009), or at two points (Devoogdt, et al., 2011), or a summated total of >2 cm (Harris, et al., 2001) or >5 cm (Hayes, Janda, Cornish, Battistutta, & Newman, 2008b) between the affected and non-affected arm. Volume of > 200 ml (Box, et al., 2002b), or >10% (Armer, et al., 2009) calculated from circumference, perometry or water displacement has also been used. With the measurement of extra-cellular fluid by BIS (Ward, 2009), an L-dex reading >10 (comparison of extra-cellular fluid between arms generates the index reading value) is commonly viewed as indicating clinically manifest lymphoedema (Piller, Keeley, Ryan, Hayes, & Ridner, 2009). Arm dominance and changes in fitness and weight can lead to differences in arm size and volume of lymph, all of which can affect the precision of readings. Although these measures compare the affected to the non-affected arm, arm dominance and BMI are taken into account only in BIS readings (Czerniec, et al., 2010).

Variations in lymphoedema status were recorded from four types of measurement over a 30-month period in 295 women (Hayes, Di Sipio, et al., 2011). The sum of the circumference of the affected compared to the non-affected arm >5% resulted in 22% of participants having lymphoedema, while 52% had lymphoedema when diagnosed using a validated questionnaire. Other measurements used were volume in ml >5% compared to the non-affected arm by water displacement (46.5%), and comparison of extra-cellular fluid by BIS (27%). When the four measurement criteria were combined, the incidence fell to 19%.

An Australian survey, reviewing the evidence from prospectively designed cohort studies with different diagnostic methods, reported a large incidence range but calculated the median of BCRL to be 20% (National Breast and Ovarian Cancer Centre, 2008c). This figure has been adopted by the Australasian Lymphology Association (Australasian Lymphology Association, 2011). There is evidence that improved treatments reduce the incidence, with the figure for those having sentinel node biopsy being 3-8% (Stanton, et al., 2009; Thiadens, Stewart, & Stout, 2010). While women can develop secondary arm lymphoedema up to 20 years post-surgery (Petrek, et al., 2001), it appears that most cases will appear within the first three years (Hayes, Janda, Cornish, & Newman, 2009; Norman, et al., 2009; Stanton, et al., 2009; Ward, 2009).

These statistics confirm that the incidence of secondary lymphoedema from breast cancer is significant and its diagnosis varies depending on the type of measurement used. Further, it still remains a possibility for those who have had sentinel node biopsy.

2.2.6 Early detection and diagnosis

With this lack of uniformity in diagnosing secondary lymphoedema, the need for standardisation has been advocated (Hayes, et al., 2008b; Stout Gergich, et al., 2008; Ward, 2009). BIS is recommended by many due to its ability to detect small changes in fluid, as well as taking into account arm dominance in its calculation of lymphoedema (Cornish, Bunce, Ward, Jones, & Thomas, 1996; Czerniec, et al., 2010; Hayes, et al., 2008b; Rockson, 2007; Ward, 2009). It can also be used effectively in a non-laboratory setting (Ridner, Dietrich, Deng, Bonner, & Kidd, 2009). However, it is unable to detect areas of localised lymph and fibrosis (Ward, Dylke, Czerniec, Isenring, & Kilbreath, 2011). Further, BIS does not measure volume of lymphoedema or tissue density.

Volume and circumferential readings are used by many clinicians. An ongoing prospective longitudinal study (n=211), with pre- and post-operative assessments every six months over 12, 30 and 60 months respectively, compared methods of diagnosis from volume, circumference and self-report by women. It showed that volume >10% provided the most conservative diagnosis, along with self-report of symptoms, while circumference >2 cm at any matched location along the arm was the most liberal (Armer & Stewart, 2005; Armer & Stewart, 2010; Armer, et al., 2009). A study of 87 women found a high correlation between volume by water displacement (once considered the gold standard for diagnosing lymphoedema) and circumferential readings that used the truncated cone formula to calculate arm volume (Tewari, Gill, Bochner, & Kollias, 2008). This study recommended that volume from circumferential readings be the method used to diagnose lymphoedema in an RCT comparing the effects of sentinel node biopsy with those of axillary clearance, undertaken by the Australian College of Surgeons (the SNAC trial)(Wetzig, et al., 2005).

The optimum time for measurement is also a factor, as early post-operative swelling may be confused with lymphoedema and lead to incorrect diagnosis. However, an increase in fluid at six months has predicted lymphoedema at 12 months (Box, et al., 2002a; Hayes, et al., 2008a) and early, mild lymphoedema can lead to more severe lymphoedema (Norman, et al., 2009).

The use of pre-treatment measurement is suggested as one reliable way in which comparison can be made with post-treatment levels of swelling and thus aid the diagnosis of lymphoedema (Mahamaneerat, et al., 2008; Piller, et al., 2009; Stout Gergich, et al., 2008). It is further recommended that regular and standardised measurement be carried out at set times in the first 12 months and up to three years, in order to monitor fluid changes (Piller, et al., 2009).

Women describe lymphoedema in their own terms and may have an awareness of their impaired lymphatic system that measuring tools are unable to detect; so, self-report is recommended as an adjunct to the assessment of lymphoedema (Piller, 2007). A prospective study of 631 women after breast cancer treatment who were monitored over five years and measured at various time-points by questionnaire, found that the sensation of heaviness and tight jewellery were predictors of lymphoedema. It also found that women who experienced mild lymphoedema were different from those without lymphoedema and that they were three times more likely to develop moderate lymphoedema (Norman, et al., 2009). In contrast, a post-surgery trial of women after axillary dissection found that, although the women in the group who undertook resistance training and had no activity restrictions (n=104) had higher sensations of heaviness and pain than those in the control group who had activity restrictions and followed usual care (n=100), there was no correlation between their report of pain and heaviness, and lymphoedema (Sagen, Karesen, & Risberg, 2009).

In studies that compared self-report and measuring methods, one found a high correlation between women's self-report and the measurement from BIS (Czerniec, et al., 2011). Another found a high correlation between the self-report of tightness and swelling and BIS and the sum of circumferential readings (Ridner, Montgomery, Hepworth, Stewart, & Armer, 2007). A third found heaviness and swelling were predictive of lymphoedema when compared with circumferential readings (Armer, Radina, Porock, & Culbertson, 2003). In contrast, Hayes and colleagues (2008b) found 40% over-reporting of lymphoedema from women's self-report compared with BIS or the sum of circumferential readings.

Considering this high degree of variation, it has been recommended that diagnosis be made by qualified and trained personnel using a range of standardised equipment for specific purposes (Lymphoedema Framework, 2006). This includes women's own perceptions. The current view promotes early detection and early treatment of lymphoedema in order to prevent the condition worsening (Lymphoedema Framework, 2006; Piller, 2007; Ridner, et al., 2007).

2.2.7 Treatment of lymphoedema

2.2.7.1 Complex lymphoedema therapy (CLT)

Early detection and treatment appear to prevent the progression of lymphoedema and may limit the formation of adipose tissue, fibrosis and infection (Moseley, Carati, & Piller, 2007; Poage, Singer, Armer, Poundall, & Shellabarger, 2008; Rockson, 2006). Treatment is usually in stages. Stage one is known as CLT, which is usually given over several days (Australasian Lymphology Association, 2009). It consists of MLD performed by qualified lymphoedema therapists, compression bandaging, prescribed exercises with deep breathing, elevation of the limb, skin care, and the development of a self-management program. Patient

compliance is necessary for this method to be most effective (Foldi, 1998). Stage two is regular MLD, the wearing of a correctly fitted compression sleeve and education about self-management. Self-management includes self-massage, specific exercises with deep breathing, elevation, skin care and risk reduction (Lymphoedema Framework, 2006).

Benefits of this approach include volume reduction (Casley-Smith, Boris, Weindorf, & Lasinski, 1998; Jeffs, 2006; Moseley, et al., 2007; Szuba, Cooke, Yousuf, & Rockson, 2000) and improved ROM of the arm when early intervention occurs (Box, et al., 2002b). A systematic review of therapies for lymphoedema volume reduction concluded that the more intensive and professional therapy-based interventions produced the best results (Moseley, et al., 2007).

The principles behind these therapies rely on clearing lymph pathways, opening collateral pathways, and creating pressure changes so that lymph will flow. Deep diaphragmatic breathing causes a decrease in intra-thoracic pressure on the inhalation and the held breath after the inhalation, and an increase in abdominal pressure below the diaphragm. Then, a long, slow exhalation reverses the pressure change leading to the emptying of the lymph through the lymphatic ducts in the upper thorax back into the venous system (Brennan, 1992; Vaqas & Ryan, 2003). The pressure needs to be maintained for a few seconds; hence the focus on the slow breath with breath retention, which creates the pressure change enabling the lymph to flow and empty at the lymphatic ducts. A pathway is thus cleared for the lymph to continue to flow rather than become blocked (Ryan & Narahari, 2012). Deep breathing is usually recommended before MLD and exercise therapy.

MLD and remedial exercise are based on the principles of clearing lymph nodes and lymph proximally and then, when those are cleared, clearing them distally. Collateral pathways can also be opened to enable the lymph to flow to functioning nodes (Casley-Smith, et al., 1998). Compression from bandaging and sleeves creates pressure changes from high at the finger tips to low at the top of the arm, which maintains the flow of lymph, prevents fluid accumulation and maintains the reduction in swelling achieved by the other methods (Carati, et al., 2009). Slow isotonic, rather than isometric, muscle contraction assists the flow of lymph (Pain & Purushotham, 2000). The effect of elevation after remedial exercise further reduces the volume of lymphoedema, due to the decrease in hydrostatic pressure of the venous system, which prevents the leaking of arterial fluids into the interstitial spaces (Vaqas & Ryan, 2003).

2.2.7.2 Self-Management of symptoms

As lymphoedema is incurable, compliance with self-management techniques is necessary and life-long. Women can find the options for self-management tiring and time-consuming (Ridner, et al., 2012). Compliance can be low when doing it at home and alone

(Bracha & Tamar, 2010) and is affected by how much a woman feels the method is working (Ridner, et al., 2011). However, compliance was found to be high in women with high levels of lymphoedema, but they then felt burdened by the amount of time needed for daily self-management and as a result, had lower QOL than those who spent less time on self-management (Ridner, et al., 2011).

Further, many women feel frustrated by the lack of knowledge and advice given by healthcare providers about self-management of lymphoedema. This was one of the major themes emerging from an analysis of the writings of 39 women about their deepest concerns from having lymphoedema (Ridner, et al., 2012).

Compliance with self-management techniques can be related to what is a usual daily regime, such as skin care, and what requires the least time (Sherman & Koelmeyer, 2011), which may be why the most practised self-management techniques for one group of women (n=51) were avoiding sunburn and cuts, not lifting heavy items, looking after the skin and wearing a compression sleeve (Ridner, et al., 2011). Self-management techniques can differ from what therapists suggest and can include pharmaceutical treatments such as pain medications, gel, cortisone and lay techniques such as drinking water, resting, exercising, and wearing loose clothing (Radina, Armer, Daunt, Dusold, & Culbertson, 2007). This supports the notion that if women think it works, irrespective of the technique, they will use it (Moseley & Piller, 2007a).

2.2.7.3 Other treatments

Various other treatments are used, some of which have clinically observed positive outcomes and various levels of research supporting their use. A review of current practices stated that treatments that needed further research included low level laser, pneumatic pumps, oscillation therapy and hyperbaric oxygen chambers. Treatments not recommended were drug-based, such as diuretics and benzopyrenes. While surgical intervention was found to be beneficial for some severe levels of lymphoedema that do not respond to other treatment, the review recommended it be used cautiously (Poage, et al., 2008).

2.2.8 Effects of lymphoedema

The effects of lymphoedema include physical and psychosocial effects from the swelling of the affected arm and its associated tissue changes and symptoms. The possibility of infection is always present and often encountered (Rockson, 2001). Arm morbidity, as a consequence of breast cancer treatment and lymphoedema, continues to affect physical activities. QOL may be reduced in domains affecting physical, social, personal and emotional wellbeing (Keeley, et al., 2010). Lymphoedema imposes a financial burden on

those women who need treatment, especially if they live in a rural area (Morgan, et al., 2005; Ridner, 2009; Thomas-MacLean, et al., 2005).

2.2.8.1 Physical Effects

Upper body function is impaired in women with lymphoedema (Beaulac, et al., 2002; Koelmeyer, et al., 2010) and can be worse in women with lymphoedema than in those treated for breast cancer without lymphoedema (Hayes, et al., 2008a; Hayes, Battistutta, Parker, et al., 2005; Pyszel, et al., 2006).

Women report a number of physical limitations from lymphoedema, firstly from the actual size of the affected arm (Passik & McDonald, 1998) and its associated sensations which include heaviness, aching, numbness, tightness and coldness (Armer, et al., 2003; Norman, et al., 2009; Ridner, et al., 2011). Pain (Dawes, et al., 2008), fatigue (Armer, et al., 2003) and lack of sleep (Ridner, et al., 2011) can also limit women's physical function.

In addition to these physical effects, the ROM and strength of the affected arm can be impaired from the swelling and fibrosis of the tissue (Armer, et al., 2003; Morgan, et al., 2005), which women with BCRL describe as a restrictive stiffness in their shoulder or hand (Girgis, Stacey, Lee, Black, & Kilbreath, 2011). Fibrosis can be in the affected area, chest and upper back and becomes worse if lymphoedema is untreated (Brennan, 1992). Fibrous tissue appears to block the flow of lymph and may prevent lymphangiogenesis, which is the formation of new lymph vessels (Piller, 2007). Fibrosis can also cause pain and altered neuromuscular coordination, which further impairs physical function (Crosbie, et al., 2010; Malicka, Barczyk, et al., 2010; Schrale & Ryan, 2011; Shamley, et al., 2009). The shoulder can have reduced ROM in the actions of internal rotation, abduction, flexion and external rotation and in the strength actions of flexion, internal rotation, extension and horizontal adduction (Johansson, et al., 2001; Johansson, et al., 2005). Women with BCRL report difficulty with carrying heavy items, repetitive arm actions, having their arm in one position or some hand actions, all of which transfers into problems with daily activities such as household chores, driving, hobbies, carrying grandchildren and doing work which requires fine motor coordination of the hand (Norman, et al., 2009; Ridner, et al., 2012; Thomas-Maclean, et al., 2008).

Studies reporting on postural changes in women with BCRL describe the asymmetry caused by the swelling and the heavier arm (Rostkowska, et al., 2006), which affects arm swing in walking and general arm movements (Balzarini, et al., 2006). This latter study found no greater incidence of thoracic kyphosis and lumbar lordosis in women with BCRL than in healthy, age-matched women. However, it did report that, although the 16 participants had no apparent spinal changes, there was a common occurrence of dropped shoulder. Both dropped shoulder and kyphosis have described the posture of women in another study of

women who had mastectomy and axillary dissection, but who did not have lymphoedema (Shamley, et al., 2007). While postural type varies according to age and other shoulder impairments (Ball, Cagle, Johnson, Lucasey, & Lukert, 2009; Edmondston & Singer, 1997; Fon, Pitt, & Thies, 1980), it is another aspect that needs to be considered in any physical therapy for women with BCRL (Hayes, et al., 2012).

2.2.8.2 Physical impairment, physical activity and quality of life

Women with BCRL can have significantly lower QOL in all domains than those treated for breast cancer without lymphoedema (Beaulac, et al., 2002; Pyszel, et al., 2006). However, the relationship between lymphoedema, physical impairment, physical activity and QOL is inconsistent and variable.

The Iowa Women's Health Study (IWHS) investigated the impact of lymphoedema and arm impairment on QOL after treatment for breast cancer (Ahmed, Prizment, Lazovich, Schmitz, & Folson, 2008). Three groups of breast cancer survivors with an average time since surgery of eight years, completed validated questionnaires for QOL, lymphoedema and arm impairment. QOL was significantly reduced in those with lymphoedema (n=104) and those with arm impairment and no lymphoedema (n=475) compared to those without lymphoedema or arm impairment (n=708). Another study compared the effect of lymphoedema and arm impairment on QOL in women seven to eight years post-treatment (Nesvold, Reinertsen, Fossa, & Dahl, 2011). It used validated questionnaires and a previous clinical assessment of 187 women, 42 of whom had BCRL, and found that pain and the degree of arm impairment, especially restricted ROM, lowered QOL more than lymphoedema alone.

The severity of lymphoedema can lower QOL in some women (Launois, Megnigbeto, Poquet, & Alliot, 2002). However, perception of the swelling, rather than the actual volume of swelling, caused one group of women (n=64) to have less confidence, especially in their body image, and to experience psychological distress (Ridner, 2005).

Physical activity levels can affect QOL. A study comparing the QOL of women with breast cancer (n=64) and that of women with BCRL (n=64) found that those with lymphoedema engaged in less physical activity and had a lower QOL (Ridner, 2005). Less physical activity has also been associated with higher BMI, which can worsen both lymphoedema and QOL (Ridner, 2005; Sagen, Karesen, Sandvik, et al., 2009). Another study which tracked 157 women after breast cancer treatment, 20 of whom had lymphoedema, over five years found that the women's QOL improved, irrespective of lymphoedema, but that it was correlated with the amount of physical activity pre-surgery and at the current time (Sagen, Karesen, Sandvik, et al., 2009). In an exercise intervention for women with BCRL

(n=31), the participants reported improvement in their QOL, in spite of the volume of arm lymphoedema not decreasing (Johansson, et al., 2005).

A number of studies have reported that women feel confused about how much they can safely do with their affected arm for fear of exacerbating the lymphoedema, and that this fear leads to a reduction in physical activity, adversely impacting on QOL (Hayes, Reul-Hirche, & Turner, 2009; Lee, Kilbreath, Sullivan, Refshauge, & Beith, 2010; Lee, et al., 2009; Towers, Carnevale, & Baker, 2008). In fact, Hayes and colleagues (2009) reported that the women in a combined aerobic and resistance RCT needed reassurance that their lymphoedema was not worsening. Once the women were measured and realised that lymphoedema levels had not increased, they were happy to continue with the exercise trial. The researchers noted that, had this not been a study, the women would not have continued with the physical activity.

2.2.8.3 Quality of life

Women with BCRL have QOL issues that are unique to them. They report that the swelling in their arm constantly reminds them of their breast cancer experience and this can create anxiety, fear and uncertainty (Ridner, et al., 2012; Towers, et al., 2008). They have a negative body image (Ridner, et al., 2012; Speck, et al., 2010), which also affects their relationships (Morgan, et al., 2005; Towers, et al., 2008) and sexuality (Girgis, et al., 2011). This detrimental image of self can lead to lack of confidence, power and control (Koelmeyer, et al., 2010; Ridner, 2005). Interviews with 12 women indicated that their lowered self-perception was felt in three ways: the negative attitudes of other people, their sense of having a chronic illness, and their inability to cope both physically and emotionally (Johansson, et al., 2003). This was reflected further in the descriptive writings of 39 women, in which 77% expressed strongly the impossible wish that they could return to normal rather than continue to live with the uncertainty imposed by an incurable condition (Ridner, et al., 2012).

Marginalisation due to lack of support from the healthcare system was expressed by 90% of women in the same study (Ridner, et al., 2012). This theme has been mentioned in many studies (Johansson, et al., 2003; Towers, et al., 2008) and is compounded when women live rurally. Rural women (n=12), living in different areas of New Brunswick, Canada, reported frustration at having to travel long distances for lymphoedema treatment, which was locally scarce (Thomas-MacLean, et al., 2005). These comments were supported by the 13 women in another Canadian study who also yearned to be normal, but felt alone and neglected (Greenslade & House, 2006). The cost of treatment and compression sleeves is also a burden that must be faced by women in Canada (Towers, et al., 2008) and Australia (Girgis, et al., 2011). An incident cohort study of women treated for breast cancer with (n=180) and without lymphoedema (n=1697) in the USA found that those with BCRL had significantly higher

medical costs and were twice as likely to have infections necessitating medical treatment in the first two years after surgery (Shih, et al., 2009).

Many of these studies reported on the poor level of information about lymphoedema that women received pre- and post-surgery. However, it appears that when education is given, the advice is heeded. A cross-sectional study (n=136) investigated the effect of lymphoedema education that was given to a group of women during treatment (57%), compared to a group who did not receive the information (43%). Those receiving the information had fewer symptoms than those who did not, leading the researchers to propose that education guidelines may reduce the risk of BCRL (Fu, Chen, Haber, Guth, & Axelrod, 2010). This was reflected further in another study conducted among 106 women who had axillary or sentinel node dissection (Sherman & Koelmeyer, 2011). The women were given, at the time of surgery and three months later, a self-reporting questionnaire investigating their level of knowledge about lymphoedema and risk-minimising behaviour. The researchers found that the women **had** received education about lymphoedema. Moreover, there was a high adherence to most risk-management strategies to prevent lymphoedema, and risk-minimising behaviour was more common among the women who had gained the information through pamphlets distributed personally by breast care nurses. These studies highlight the benefits of education, especially when given by a breast care nurse.

Although many of the QOL studies are small, they do emphasise the degree to which women's lives are adversely affected on physical, social and emotional levels. In spite of this, women also report the positive effect on QOL that comes with having a sense of connection, either through their spirituality, their family or their friends (Ridner, et al., 2012; Towers, et al., 2008), or by attending group exercise classes (Bracha & Tamar, 2010; Hayes, Reul-Hirche, et al., 2009). It is clear, from the above discussion, that women with BCRL have physical and psychosocial effects from living with lymphoedema and that all aspects of their lives need to be considered in any kind of treatment or therapy.

2.2.9 A holistic approach

The need for a holistic approach to BCRL has been suggested by various researchers over time (Passik & McDonald, 1998; Ridner, 2005; Ridner, 2009). A review of qualitative and quantitative studies on QOL concluded that, given the diminished QOL which results from the complexity of the physical, psychological and emotional effects of lymphoedema, a multidisciplinary approach based on the individual as a whole person was of paramount importance (Morgan, et al., 2005).

This is reflected in the guidelines of *The International Consensus Document* for the best practice of lymphoedema (Lymphoedema Framework, 2006), the National Lymphoedema

Network USA (2011a) and the Australasian Lymphology Association (2011), all of which advocate the need for education, early identification and appropriate holistic treatment of lymphoedema, including addressing issues adversely affecting QOL.

2.3 Exercise and lymphoedema

Lymph can be propelled passively, as in CLT and MLD described above, or by movement of the muscles and diaphragm, as occurs during exercise. It is related to the response of the sympathetic nervous system (Lane, Worsley, et al., 2005). Exercise was once considered a risk factor for lymphoedema as it was thought the increased flow of blood would put further pressure on the damaged lymph system and increase the swelling (Flew, 1979). The actual aetiology of what happens to the lymphatic system during bouts of exercise is largely unknown. However, studies using lymphoscintigraphy are becoming more common in an attempt to provide this information (Modi, et al., 2007; Stanton, et al., 2009).

For those women at risk of or having BCRL, the aim of exercise is to improve overall health and fitness, daily function and QOL without causing or exacerbating lymphoedema (Cheifetz & Haley, 2010; McNeely, Peddle, Yurick, Dayes, & Mackey, 2011). Exercise, with specific safety guidelines, is now recommended as an essential component of post-surgery treatment (Schmitz, 2011). Research has established that lymphoedema is not exacerbated or caused by post-surgery physiotherapy and resistance training, nor is lymphoedema exacerbated across a range of exercise modalities, under supervised and controlled conditions, in those with existing BCRL.

2.3.1 Post-surgery exercise

Post-surgery physiotherapy for women at risk of lymphoedema has consistently resulted in similar or reduced rates of lymphoedema in those in the physiotherapy intervention group compared to those in the control group (Beurskens, van Uden, Strobbe, Oostendorp, & Wobbes, 2007; Lacomba, Sanchez, Goni, Tellez, & Mogollon, 2010; Portela, Santaella, Gomez, & Burch, 2008). These results have also been found in trials comparing the effects of immediate and delayed exercise interventions (Bendz & Fagevik Olsen, 2002; Cinar, et al., 2008).

An RCT based on physiotherapy was conducted on women with axillary dissection immediately post-surgery. Its aims were to evaluate the effectiveness of progressive post-surgery physiotherapy in restoring shoulder ROM and to monitor lymphoedema incidence. Education about lymphoedema risk and lymphoedema therapy was also given to the intervention group (n=32). The control group (n=33) received an exercise booklet. Measurements were taken pre-surgery and at various times over a two-year period. After two years, 11% of the women in the intervention group, compared to 30% in the control group,

had lymphoedema. The researchers concluded that lymphoedema incidence was reduced and its effects controlled more effectively in the intervention group for up to two years after surgery (Box, et al., 2002a).

Further, post-surgery resistance training trials have not led to an increase in lymphoedema incidence. An RCT compared two groups of women post-axillary dissection surgery (Sagen, Karesen, & Risberg, 2009). The intervention group (n=104) was instructed to have no activity restrictions and received resistance training two-three times a week, while the control group (n=100) was told to restrict its activity and follow usual care, over a six-month period post-surgery. Measurements were taken pre-surgery and post-surgery at three and six months with a two-year follow-up. The result was the same level of lymphoedema, 19% in both groups, at the two-year measurement. Another trial (Ahmed, Thomas, Yee, & Schmitz, 2006) focussed on comparing women with axillary dissection taking part in weight-training 4-36 months post-treatment (n=23) with a control group following usual care (n=22). In this trial, some women already had lymphoedema. After six months, there was neither exacerbation of existing lymphoedema nor increased incidence of lymphoedema in the resistance training group. The researchers advised that women can safely take part in activity and resistance training after breast cancer surgery, even those at risk of lymphoedema.

Other studies for at-risk women have shown that strenuous exercise, such as dragon boat-racing (Harris & Niesen-Vertommen, 2000) and aerobic or resistance training during chemotherapy (Courneya, et al., 2007), did not cause lymphoedema.

Despite the apparent long-term benefits of post-surgery exercise in reducing the incidence of BCRL, the exercise needs to be targetted appropriately. Early elevation of the arm post-surgery is potentially detrimental, with a study finding that elevating the arm more than 90° in the first week post-surgery led to a significantly higher lymphoedema incidence at the one-year measurement than in those who received physiotherapy post-surgery but whose full ROM was delayed by one week (Todd, Scally, Dodwell, Horgan, & Topping, 2008).

2.3.2 Effects of exercise on women with BCRL

The notion of exercise being beneficial for women with BCRL is not new. An individualised exercise program focussing on flexibility, ROM and strength, as well as aerobic conditioning, was recommended in 1998 (Brennan). A small, early study (n=14; control=7, intervention=7) into the effect of resistance and aerobic exercise on women with BCRL showed that lymphoedema did not worsen and that QOL improved and so recommended further larger trials take place (McKenzie & Kalda, 2003).

A review of randomised and cohort controlled trials on exercise and lymphoedema, specifically those focussing on volume and symptom reduction, concluded that exercise

seemed to lower the level of lymphoedema and reduce symptoms (Moseley & Piller, 2008). While all studies had small numbers of participants, the types of exercise reviewed included hydrotherapy, *tai-chi,* resistance exercise with weights and dragon boat-racing. The authors suggested that having an option to do different types of exercise, such as those reviewed, would give women a wider choice, assisting in maintaining the motivation for self-treatment as an alternative to more expensive treatment.

More recently, a single-blind RCT showed that a 12-week combined aerobic and resistance exercise program did not exacerbate lymphoedema. However, once again the sample size was small (16 in each group) and not all the control group had the qualifying amount of lymphoedema (Hayes, Reul-Hirche, et al., 2009).

Another study of 16 women without lymphoedema who had been treated for breast cancer and who took part in a mixed exercise program of aerobic, resistance and dragon boat-racing over 20 weeks, showed in fact that both arms increased in volume as well as in strength. The researchers postulated that an increase in arm volume from exercise could also be a result of muscle hypertrophy (Lane, Jespersen, & McKenzie, 2005).

The largest exercise intervention to date, the Physical Activity and Lymphedema Trial (PAL), in which 141 women with BCRL were included as control (n=70) or intervention (n=71) in a year-long resistance training intervention, showed that there was no increase in lymphoedema, that the incidence and severity of lymphoedema exacerbations and hand and arm symptoms decreased, and that strength increased (Schmitz, Ahmed, et al., 2009). The researchers concluded that supervised resistance training with adequate warm-up and cool-down, and gradual progression of difficulty, did not have adverse effects on lymphoedema. A further positive outcome of this trial was the significant improvement in body image experienced by the participants (Speck, et al., 2010).

A recent systematic review reflected the findings of the above studies (Kwan, et al., 2011). Nineteen exercise studies were reviewed for people with lymphoedema and those at risk of lymphoedema, particularly from breast cancer, and included resistance (seven), aerobic and resistance-type (seven), and other exercise modalities (five), including home-based exercise. The authors concluded that resistance exercise was likely to be effective, aerobic and resistance-type exercise appeared safe but needed longer and more rigorous trials, while the variety of type and duration of other exercise modalities meant more investigation was required. Importantly, it confirmed that lymphoedema was not worsened by a systematic progression of exercise.

2.3.3 Gentle exercise incorporating breathing and relaxation for BCRL

Breathing and gentle exercise have been used therapeutically as a self-management tool for BCRL. Casley-Smith (1999) developed gentle isotonic exercises following the principles of MLD by systematically clearing the proximal to distal lymph nodes. These exercises commenced and finished with relaxation and slow breathing, preferably with elevation of the affected arm. During the exercises, specific breathing, using an exhalation with a strong abdominal contraction, was used to clear the lymphatic ducts to allow space for the lymph to flow. When applied to the self-management of lymphoedema by individuals (Casley-Smith, et al., 1998), to physiotherapy groups (Bracha & Tamar, 2010) and to aquatic exercise groups (Tidhar & Katz-Leurer, 2010), these principles have improved the QOL in women with BCRL without increasing lymphoedema levels.

In contrast, a debate on the actual effect of deep breathing and gentle movement on lymphoedema revealed varying points of view (Piller, Craig, Leduc, & Ryan, 2006). While participants generally agreed that movement was beneficial for lymphoedema, there was no consensus on the effect of deep breathing. Those that argued against the use of deep breathing said the actual physiology had no well-supported proof, while those that argued for it supported the principle expounded by Casley-Smith (Casley-Smith, et al., 1998), namely that the pressure changes caused by slow, deep breathing empty the lymph at the lymphatic ducts back into the venous system.

A trial to specifically test the effect of deep breathing with a *tai-chi* type exercise had positive results (Moseley, et al., 2005). The four-week trial on 24 women, with a comparison control receiving usual care, performed a twice-daily ten-minute arm exercise with deep breathing by opening and closing the arms at chest height, tensing the arms on the pause after the inhalation and bringing the arms back to the chest on the exhalation while releasing the tension. The authors hypothesised that deep breathing and gentle movement would create pressure changes to systematically empty the lymphatic ducts and improve lymphatic drainage from the affected limb. Compared to the control group, there was a slight decrease in lymphoedema levels and significant subjective improvements occurred in the sensation of heaviness and the perception of limb size. Compared to the control group, there was also a significant reduction in chest tissue density in the intervention group, perhaps, the researchers postulated, caused by the gentle movement of the exercise softening the adhesions and fibrosis of the chest tissue.

Another small RCT used daily therapy that combined slow and gentle movement with deep breathing, imagery and music to promote a relaxed state, before finishing with an unspecified relaxation (McClure, et al., 2010). The intervention consisted of five weeks of a bi-weekly hour-long group class, and a daily 17-minute home-practice, followed by three

months of daily home-practice. The authors hypothesised that the sequencing of the movements with breathing would promote lymph flow and thoracic emptying, while at the same time decreasing stress and negative mood, leading to improved immune function in what they described as a "circle of healing." They further hypothesised that symptoms of lymphoedema would decrease. At the completion of the trial, the intervention group (n=10) had a reduction in arm swelling and significant improvements in weight loss, internal rotation, summated shoulder ROM (flexion, abduction, external rotation), mood and QOL, compared to the control group (n=11) which had continued with usual care.

The abovementioned trials support the notion that exercise, breathing and relaxation do not exacerbate lymphoedema levels and, in fact, improve symptoms, physical components such as shoulder ROM, and QOL in women with BCRL. In this way, they offer another option for women to manage BCRL.

2.3.4 Exercise guidelines

Exercise guidelines for women with BCRL have changed to reflect the beneficial outcomes that have been observed (Schmitz, 2009). The current advice is that exercise appears safe but needs to be supervised and given on an individualised basis (Poage, et al., 2008). It should be slowly progressive with adequate rests and risk reduction pertinent to those with lymphoedema or those at risk. Recommended exercise includes remedial exercises, flexibility/stretching, resistance training and aerobic conditioning (National Lymphedema Network, 2011b).

2.4 Complementary and Alternative Medicine (CAM)

Women undergoing treatment for breast cancer are high users of CAM, which includes yoga and meditation (Cancer Institute NSW, 2009; Greenlee, et al., 2009; Kremser, et al., 2008). In relation to lymphoedema, an Australian cross-sectional study investigated the use of CAM and its relationship with mainstream medicine as treatment for lymphoedema after breast or gynaecological cancer, by sending a questionnaire to members of a lymphoedema association (Finnane, et al., 2011). It reported that half of the respondents (n=95) used 27 different types of CAM, in addition to their mainstream treatment. The use of a chi machine, participation in yoga and meditation and consumption of vitamin E were the most common. Respondents rated the effectiveness of CAM as similar to that of mainstream therapies. The authors recommended further research into the relationship between CAM and mainstream therapy for lymphoedema. Another cross-sectional study looked into the unmet needs of 237 women with lymphoedema (Girgis, et al., 2011). A major finding was that participants wanted to know more about both conventional and alternative treatments for lymphoedema.

Well-designed studies into the effect of CAM on lymphoedema have been recommended by lymphoedema researchers (Bernas & Witte, 2004). Yoga is considered a complementary therapy. As an integrated practice, it also has commonalities with exercise and other components of therapy used in lymphoedema management, such as long, slow breathing, progressive movement incorporating mobility and strength, relaxation and arm elevation. The need for research into the effect of yoga on BCRL has been pointed out by various lymphoedema researchers (Moseley, et al., 2005; Ridner, 2005; Schmitz, 2009).

An extensive integration of CAM and western medicine has been formalised in Kerala, India, specifically for lymphoedema of the lower limbs from filariasis. The CAM component consists of Ayurveda, yoga therapy and naturopathy. The medical component consists of the medical practices of dermatology (Narahari, et al., 2011). The combination of these therapies took five years to develop but has resulted in a successful holistic treatment for lower limb lymphoedema (Bose & Aggithaya, 2011). It is possible, therefore, that western medicine and CAM, including yoga, could have transferrable outcomes for women with BCRL.

2.5 Yoga

2.5.1 Philosophy

The term "yoga" comes from the Sanskrit root *yuj* which means joining or union (Feuerstein, 1975). The concept of *union* in yoga is that each individual has the potential and ability to create unity and balance in their internal and external worlds beyond any personal physical limitation (Iyengar, 2001; Nirmalananda, 2009).

The practices of yoga provide the means to do this. There are many practices, so that each individual can find their own path. These practices have developed over thousands of years from the Indus and later Aryan civilisations in India (Feuerstein, 1975), as an oral and then written tradition recorded in many texts over centuries, such as the *Vedas, t*he *Upanishads*, the *Bhagavad-Gita*, *The Yoga Sutra*, *Hatha Pradipika*, *Gheranda Samhita* and *Yoga Vasistha* (Nagarathna, 2006). The three main philosophies that have influenced yoga, *Samkhya*, *Vedanta* and *Tantra,* provide the method and practices for individuals to obtain personal awareness and gain liberation. Yoga, therefore, has a rich and informed philosophical and practical base that is not founded on religion or theology (Saraswati, 1993).

2.5.2 Yoga in the West

At the Parliament of the World in 1893, the spread of the philosophy of yoga to the West was formalised in a talk by Swami Vivekenanda. The continual interchange between India and the West, that had no doubt commenced before that time, has led to the current popularity of yoga in the West and the subsequent development of many traditional (for example, Vivekenanda, Iyengar, Satyananda Yoga®) and newer styles (for example, Bikram,

Anusara), each with different interpretations and practices within the core belief of yoga creating "union".

According to the Australian Bureau of Statistics (ABS), 311,000 people or 2.1% of the adult population participated in yoga in 2002 (Australian Bureau of Statistics, 2002). In 2005-2006, ABS figures reported that yoga was among the top 10 most popular physical activities for women, with a 3.1% participation rate by the female population (Australian Bureau of Statistics, 2012); however, yoga was not included in the report for Australian males. An American survey in 2008 (Yoga Journal, 2008) stated that yoga had a 6.9% participation rate, with 72.2% being women. A study in England (Sport England, 2002) quoted the figure of 17% of women and 7% of men doing keep fit/yoga.

Health issues are one reason many people commence yoga. Studies in Australia and the USA have reported that general practitioners regularly refer their patients to yoga and meditation (Cancer Institute NSW, 2009; Cohen, Penman, Pirotta, & Da Costa, 2005; Yoga Journal, 2008). In his thesis *Yoga in Australia: Results of a national survey* (2008), Penman reported that 20% of the 3892 respondents to his survey took up yoga for a specific health issue, while the American survey (Yoga Journal, 2008) reported that half of its respondents (n=5050) started yoga to improve their overall health. According to Penman's survey, most Australian yoga practitioners are well-educated women in their 40s, who begin yoga for physical reasons or for the management of specific health issues or stress. Women with BCRL in Australia are part of the population which is participating in yoga for health-related reasons (Finnane, et al., 2011); hence the need for well-designed studies to research the effect of yoga on lymphoedema in the same way that the effects of exercise have been researched.

2.5.3 Yoga as an integrated practice

Although many styles of yoga exist and continue to develop, modern yoga is largely informed by an integrated approach outlined in the text *The Yoga Sutra*, by Patanjali. This text defines how the progression and integration of the different aspects of yoga can lead to individual transformation to bring about the previously described *union*. This union of the internal and external selves can also be referred to as freedom (Saraswati, 1980).

Written in the form of short aphorisms around the second or third century AD (Feuerstein, 1975), the practices outlined in *The Yoga Sutra* are known as the eight limbs or stages of yoga (*ashtanga*) and progress from practices to help each individual function in society to more transcendental practices of meditation.

The practices begin at the level of daily life:

1. *Yama* focus on community behaviour; for example, *Ahimsa* or non-violence in action or word;
2. *Niyama* focus on self-care; for example, *Svadhyaya* or self-study;
3. *Asana* are the postures that develop physical health;
4. *Pranayama* are energy-expanding practices using the breath to calm and balance the mind and nervous system.

When these practices are mastered, meditation follows:

5. *Pratyahara* develops skills to withdraw the arousal of the senses;
6. *Dharana* develops concentration by focussing on a single point, perhaps an image or a sound;
7. *Dhyana* refers to the state of merging with that point of concentration;
8. *Samadhi* is the ultimate point of finally losing all consciousness of form and time (Saraswati, 1980).

These stages develop both mental and physical awareness. Awareness, Patanjali writes, is the ability to be totally in the present moment as an observer, and so the fluctuations of the mind are controlled. From this state an individual can develop *viveka* (discernment) and *vairagya* (detachment) and can thus transform their life. From this transformation each individual then has the ability to experience liberation and *samadhi* (Saraswati, 1993).

2.5.4 Yoga and disease

According to the philosophy of yoga, disease is a result of disruption to the mental, energetic and physical aspects of self, which can be caused by a variety of intrinsic and extrinsic factors. Each individual consists of five overlaying layers called sheaths (*kosha*), known as the physical (*annamaya*), energy (*pranamaya*), mental (*manomaya*), wisdom (*vijnanamaya*), and bliss (*anandamaya*) sheaths. A disturbance in one will affect another and then another, leading to eventual illness which becomes apparent in the physical body. For example, the Vivekenanda tradition of yoga describes disturbances in the mental sheath which lead to too much or too little energy in the energy sheath and over time, this will cause a change in the physical sheath and the body will become ill (Nagarathna, Nagendra, & Telles, 2006).

Satyananda Yoga® describes disease as beginning as an imbalance in any of the physical, energy or mental sheaths, and as this imbalance accumulates, the energy sheath is adversely affected, which in turn transforms into symptoms of illness in the physical sheath

(Saraswati, 1993). The imbalance in the first three sheaths can also be affected by negative patterns in the fourth sheath, the wisdom sheath. This sheath is where long-held patterns of thinking and behaviour are stored and affect all our reactions. These long-held patterns are known as *samskara* and can be personal, collective from one's culture, or karmic (occurring over lifetimes) (Nirmalananda, 2009).

Since disease is caused by the negative interrelationship of the body, energy and mind, the opposite is also true (Nagarathna, et al., 2006; Saraswati, 1996). By improving the functioning of the *kosha*, health can improve.

Added to this is the *guna* system, which describes three states of being for all living and non-living things: motion (*rajas*); inertia (*tamas*); balance (*sattwa*). The ultimate aim of yoga is to become more *sattwic* in nature. This can be achieved by fostering and maintaining awareness at any given time (Saraswati & Stevenson, 2010).

Satyananda Yoga® considers that cancer is a result of the accumulation of *tamas* in one or more *kosha*. Environmental factors can lead to toxins in the physical body (*annamaya kosha*). When the energy system (*pranamaya kosha*) of the body is not functioning well, perhaps through exhaustion or living in a polluted environment, the immune system can suffer. Negative habits and states of mind (*manomaya kosha*) can lead to further depletion of the immune system. Past negative actions (*vijnanamaya kosha*) can lead to an overriding imbalance in all thinking and action (Nirmalananda, 2009).

The reverse is also true; when all the *kosha* are balanced and functioning well, a more *sattwic* way of being is attained and an individual has the ability to connect to the bliss sheath (*anandamaya kosha*).

2.5.5 Yoga therapy

Yoga is a holistic system based on the biopsychosocial concept of health (Evans, et al., 2009), in which each individual can take responsibility for their health by following an integrated system of practices to improve the functioning of their body, mind and spirit (Desikachar, 2005; Vivekenanda, 2005). This has led to the development of yoga therapy as a complementary treatment for illness. Yoga therapy is based on the premise that physical symptoms and function can be managed or improved and that identification with the illness can be changed to improve personal and emotional wellbeing (International Association of Yoga Therapists, 2011). The expanding use of yoga therapy is supported by an increasing amount of scientific research (Evans, et al., 2009; Raub, 2002).

2.5.6 Research on yoga and its practices

The potential benefits of yoga have been investigated in studies with healthy and ill populations (Cox, et al., 2010; Hegde, et al., 2011; Oken, et al., 2004; Raub, 2002; Ward, Treharne, & Stebbings, 2011). Outcomes of research that may be transferrable to women with BCRL include the beneficial effects of yoga on pain (Bussing, Ostermann, Ludtke, & Michalsen, 2012), spinal flexibility (Tekur, Singphow, Nagendra, & Raghuram, 2008), strength (Madanmohan, et al., 1992), core strength (Omkar, et al., 2009), QOL (Rakhshani, Maharana, Raghuram, Nagendra, & Venkatram, 2010) and thoracic kyphosis (Greendale, et al., 2009; Greendale, McDivit, Carpenter, Seeger, & Huang, 2002).

Specific practices may also be of benefit to women with BCRL. Slow, full breathing, recommended in lymphoedema management to empty the lymphatic ducts and assist the flow of lymph, is an essential component of yoga. Research has shown that the full yoga breath and *pranayama,* such as alternate nostril breathing (*nadi shodan* or *anuloma viloma*), balance the sympathetic and parasympathetic nervous systems, calm the mind and provide a good preparation for meditation (Kaminoff, 2006; Saraswati, 1996; Telles, et al., 1994), all of which may be of benefit to women with BCRL. The full yoga breath also uses the secondary muscles of inhalation, the pectoral and serratus anterior muscles (Kendall, et al., 2005), which are affected by breast cancer surgery and lymphoedema.

A practice which involves a rest for an equal time after each series of postures, has been shown to engage the parasympathetic nervous system (Telles, et al., 2000) and prevent overstimulation of the sympathetic nervous system, as has been recommended in exercise guidelines for women with BCRL (Schmitz, 2009). Further, it enables the lymph system in a particular area to fully empty, and has been used for this purpose as part of yoga therapy for lower limb lymphoedema from filariasis (Bose & Aggithaya, 2011).

Relaxation, as given at the end of a yoga session, has been used therapeutically to improve the recovery process and reduce stress (Benson, 1982). It has also been recommended for enhancing QOL in women with BCRL (Augustin, Bross, Foldi, Vanscheidt, & Zschocke, 2005; McClure, et al., 2010). Relaxation reduces the sympathetic response, leading to slower heart rate and lower arterial blood pressure that also slows down the propulsion of lymph and cools down the body (Lane, Worsley, et al., 2005), essential components of lymphoedema management after exercise (National Lymphedema Network, 2011b; Schmitz, 2009). The effect of a deep relaxation known as *yoga nidra*, systematised by Swami Satyananda, was studied by using EEG electrodes on seven experienced practitioners as they followed the relaxation. It showed that, during *yoga nidra*, the alpha waves (aware and yet relaxed) and theta waves (deep relaxation) were both evident, whereas during most relaxation practices, the theta waves are predominant. The researchers postulated that it

was this combination of alertness and relaxation that created the beneficial effects of *yoga nidra* and gave it the quality of both meditation and relaxation (Nilsson, 1997).

The physical postures of yoga (a*sana*) focus on correct placement of the body, stabilisation of the joints and movement according to kinematic chains, in order to promote correct biomechanical functioning of the muscles by balancing both ROM and strength and creating symmetry between sides (Coulter, 2001). This may be of help in correcting the upper body impairment (Balzarini, et al., 2006; Crosbie, et al., 2010; Jahr, et al., 2008; Schrale & Ryan, 2011; Shamley, et al., 2009; Shamley, et al., 2007) and faulty posture (Malicka, Barczyk, et al., 2010; Malicka, Hanuszkiewicz, et al., 2010; Rostkowska, et al., 2006) experienced by women with BCRL. Yoga has a strong focus on posture. Before any physical movement commences, irrespective of body position, the body is aligned to promote postural awareness. This also occurs before meditation practices and is known as *kaya sthairyam* (Saraswati, 1993). Stabilisation of the pelvis and joints, known as *bandha* in yoga (Borg-Olivier & Machliss, 2004), is emphasised. For example, *moola bandha* and *uddiyana bandha* create core stabilisation by co-contraction of the pelvic floor and transversus abdominis muscles, and internal oblique when required (Omkar, et al., 2009). *Amsa bandha* creates stabilisation of the thoracic-scapulohumeral joints by co-activating opposing muscles such as glenohumeral abductors and adductors and scapulothoracic protractors and retractors (Borg-Olivier & Machliss, 2004). Yoga breathing also engages core muscles and at times, all the abdominal muscles (Petrofsky, Cuneo, Dial, & Morris, 2005). Further, movement patterns in yoga follow kinematic chains of progressive muscle contraction; for example, rotation of the spine engages the internal oblique, then the external oblique, serratus anterior, rhomboids, trapezius, and pectoralis minor, so that the body rotates in a stable and biomechanically efficient way (Myers, 2001).

Restoration of posture, stability and movement patterns is an essential aim of exercise for women with BCRL (Hayes, et al., 2012). As it is also an essential focus during the physical postures of yoga, it is possible that yoga could be helpful for women with BCRL.

Due to the physical components of yoga, research has compared its effects with those of exercise. A systematic review of 12 studies, including eight RCTs, compared yoga and exercise interventions. The authors concluded that yoga provided health-related outcomes as good as and at times better than exercise, in healthy and ill populations, especially in self-report of reduced fatigue, pain and stress, and improved sleep. The authors recommended that future studies need to emphasise the difference between yoga and exercise (Ross & Thomas, 2010). Although this research did not involve women with BCRL, it does suggest that yoga may have benefits similar to those found in exercise studies on women with BCRL.

Currently, there is no published research on the effect of yoga on BCRL. However, there is published research into the effect of yoga on women during and after breast cancer treatment.

2.5.7 Yoga and breast cancer research

Research has investigated the effect of yoga on women during and after breast cancer treatment with positive results in domains such as QOL, physical function, fatigue, pain, symptoms, stress and immune response, as discussed below. These may have transferrable outcomes to women with BCRL.

The effects of breast cancer have been described previously as affecting women physically, mentally, emotionally and socially. Yoga, as an integrated system, deals with all these aspects. A review of the literature on yoga and its effects on people with cancer, most of which was breast cancer, indicated that there were significant improvements across 10 studies in sleep, QOL, levels of stress and immunity (Smith & Pukall, 2009). Another review of nine studies described small, but significant, improvements in sleep, QOL, mood, stress and cancer-related symptoms (Bower, Woolery, Sternlieb, & Garet, 2005). Both reviews reported, however, that there were limitations in comparing studies and making firm conclusions, due to the various styles of yoga, different study designs with low numbers and variations in statistical analysis, and concluded that a need for well-designed RCTs exists in order to verify the results.

The Vivekenanda Research University in Bangalore (Swami Vivekenanda Yoga Anusandhana Samsthana-SVYASA) has been conducting RCTs for over 15 years and is now in partnership with medical institutions, including the MD Anderson Cancer Centre in Texas, USA and the Indian Council of Medical Research. Research trials follow women from the time of diagnosis and continue through their treatment. The intervention consists of an hour-long daily integrated yoga session. The practices are progressive and suited to the treatment protocol. Basically, they consist of forms of breathing and *pranayama*, gentle postures, relaxation, visualisation and meditation techniques. Specific practices under these categories have been developed. The control group receives supportive counselling.

These trials have resulted in improvements in QOL (Vadiraja, Raghavendra, et al., 2009) and symptom management (Vadiraja, Rao, et al., 2009) and in lowered levels of stress (Banerjee, et al., 2007), anxiety and depression (Raghavendra, et al., 2007; Rao, et al., 2009). A recent trial conducted by these researchers was held at the MD Anderson Cancer Centre and resulted in significant improvements in QOL sub-scales (Chandwani, et al., 2010). During radiotherapy, an intervention group (n=30) received twice-weekly 60-minute yoga sessions for six weeks, and was compared to a wait-listed control group (n=31). Significant results were reported in the QOL sub-scales of general health perceptions and physical functioning at the

end of the intervention. At the three-month follow-up the intervention group had a significantly greater outcome in finding a benefit in the cancer experience. This was positively correlated with the degree of intrusive thoughts. So, although the negative thoughts were constant, the reaction to them was no longer negative. The researchers speculated that this was an outcome associated with the yoga teaching of mindful awareness of all situations. However, no differences occurred for sleep disturbance, mood, anxiety or fatigue.

These improvements in QOL have been echoed in several smaller yoga studies of various traditions (Blank, Kittel, & Haberman, 2005; Bower, et al., 2011; Culos-Reed, Carlson, Daroux, & Hately-Aldous, 2004; Culos-Reed, Carlson, Daroux, & Hately-Aldous, 2006; Danhauer, et al., 2008; Speed-Andrews, Stevinson, Belanger, Mirus, & Courneya, 2010; Ulger & Yagli, 2010). Positive affect, emotional wellbeing and acceptance have also been reported (Danhauer, et al., 2009), including in a study on women with secondary breast cancer (Carson, et al., 2007). Increased spirituality (Danhauer, et al., 2009; Moadel, et al., 2007), benefits derived from a group discussion at the beginning or end of a class (Blank, et al., 2005; Carson, Carson, Porter, Keefe, & Seewaldt, 2009; Carson, et al., 2007) and the enjoyment and positivity gained from being part of a group which had been through the same disease process and treatment (Moadel, et al., 2007; Raghavendra, et al., 2007; Ulger & Yagli, 2010), have also been reported.

Studies have also investigated specific physical effects. An eight-week trial compared a yoga intervention group, measured pre- and post-trial, to a control group which did light exercise, for the effect on physical fitness, constraints to physical activity and body image (Van Puymbroeck, Schmid, Shinew, & Hsieh, 2011). The yoga group (n=18) had significant improvements in flexibility and grip strength, as well as a significant reduction in constraints to physical activity, compared to the control group (n=12), which had significant improvements in lower body endurance and abdominal strength. The yoga group also improved in body image, and reported better balance and less pain.

Only one trial has investigated the effect of yoga on breast cancer-related arm morbidity (Thomas-MacLean, et al., 2010). It reported the responses of 10 women to open-ended questions in a non-controlled study design. Following a six-week Iyengar yoga intervention, the women reported that they felt better able to manage their arm problems, were able to see their body as something beyond the illness and nine of the 10 women reported that they thought yoga had helped them to heal. The one woman who did not improve had lymphoedema, and reported instead that yoga gave her hope that her health would improve in the future.

The effect of yoga on specific effects from breast cancer treatment have also been studied. Single-arm pilot trials have reported reductions in fatigue after 12 weeks of yoga (n=11) (Bower, et al., 2011) and in the pain derived from aromatase inhibitors after eight weeks of yoga (n=10) (Galantino, et al., 2011). An RCT found reduced menopausal symptoms in the yoga intervention group (n=16), compared to the wait-listed control group (n=17), after eight weeks of yoga (Carson, et al., 2009).

The meditation practices of yoga include mindfulness practices. These have been specifically researched as part of an integrated yoga therapy for breast cancer survivors, with positive outcomes in lowered levels of stress, improved mood and QOL (Carlson, et al., 2003; Speca, Carlson, Goodey, & Angen, 2000) and reduced negative affect from treatment (Carson, et al., 2009; Carson, et al., 2007; Chandwani, et al., 2010).

Some studies have reported improved immunity by lowering cytokine production (Carlson, et al., 2007; Rao, et al., 2008) and increasing NK cells (Rao, et al., 2007). As immunity is compromised in women with BCRL (Mallon, et al., 1997), yoga therapy may be of benefit to them.

All these studies indicate the benefits of yoga as a treatment modality for breast cancer, in overall QOL and in the domains of pain, fatigue, physical function and immunity, all of which are also relevant to women with BCRL. Although there is currently no published research into the effect of yoga on BCRL, there is published research into yoga and lower limb lymphoedema.

2.5.8 Yoga and lymphoedema research

The largest body of research into yoga and lymphoedema is from a holistic treatment, based on Ayurveda, yoga therapy and western medicine, for lower limb lymphoedema caused by filariasis in Kerala, India (Narahari, Aggithaya, Prasanna, & Bose, 2010; Narahari, et al., 2011; Narahari, et al., 2007; Narahari, Ryan, Aggithaya, Bose, & Prasanna, 2008; Vaqas & Ryan, 2003). The aim is to provide self-managed and cost-effective lymphoedema treatment to people living in rural areas. The patient and family members are taught the requirements of the treatment in a hospital, then continue it in their rural setting. The therapy consists of skin treatment, yoga therapy, Indian manual lymphatic drainage (IMLD), elevation and compression. Breathing practices are included in the yoga and with the IMLD. Ayurvedic herbs are taken as well as western medicines (Narahari, et al., 2011). Patient-led support groups are encouraged, in order to further the effectiveness of the treatment (Bose, et al., 2008).

Published research on the effects of this therapy reported a decrease in the level of lymphoedema in the affected limb, less infection and less need for antibiotics in 112 patients

and 149 lower limbs over 194 days (Narahari, et al., 2007). A further report on the same study noted that higher levels of compliance led to more positive outcomes of treatment (Narahari, et al., 2010). A more recent publication described its effectiveness in 638 patients from 2003-2009 in decreasing the volume of lymphoedema and the number of inflammatory episodes. The reduction was greater for limbs with a higher volume of lymphoedema at baseline (Bose & Aggithaya, 2011).

The yoga therapy component of this treatment consists of specific yoga practices and *pranayama* that are used daily, in conjunction with IMLD, to encourage lymphatic drainage. Before IMLD, eight postures are used with specific *pranayama* to empty the lymph into the venous system at the lymphatic ducts, then to clear the lymph nodes. At a later time in the day, 10 yoga postures with the same five *pranayama* techniques are used to further lymphatic drainage, while the participant wears compression bandaging. Both yoga sessions end with leg elevation and relaxation (Narahari, et al., 2011). The researchers explain that diaphragmatic breathing with breath retention is used to promote clearing from the lymphatic trunks. Breathing slowly and in time with the sequenced postures clears the central, then the peripheral lymph nodes and the slow movements of yoga ensure the emptying of the lymph vessels. Rest time between postures further assists the complete emptying of the lymph vessels and allows the parasympathetic nervous system to be engaged. The *pranayama* used is specific; for example, a gentle form of *bhastrika* (bellows breathing) is used to empty the lymphatic ducts by focussing on exhalation with abdominal contraction; *anuloma viloma* (alternate nostril breathing) is used to balance the autonomic nervous system; and *surya bhedana* (left nostril breathing) is used to engage the parasympathetic nervous system (Bose & Aggithaya, 2011; Narahari et al., 2011; Ryan & Narahari, 2012) (personal communications, Dr Aggithaya, February-March 2012). The use of the slow exhalation by chanting, which typically commences and completes a yoga session, is believed to further empty the lymphatic ducts (Piller, et al., 2006; Ryan & Narahari, 2012).

This research is important in showing not only the benefits of including yoga therapy as part of a holistic medical treatment for lymphoedema but also for its application as part of a cost-effective method of self-care. However, whilst the results of the research are encouraging, it is uncertain which of the multiple treatments is/are responsible for the reductions in lymphoedema.

2.6 Yoga for women with BCRL

It is proposed that yoga, with slow breathing, gentle and progressive moving physical postures, meditation and relaxation, following the guidelines for exercise and risk reduction for women with BCRL recommended in the reviewed literature, will not exacerbate lymphoedema. Further, it may improve overall physical movement and posture by focussing

on the use of core and joint stability with correct kinematic movement patterns. In particular, the corrected function of the thoracic-scapulohumeral connection may reduce upper body impairment and restore symmetry of movement patterns. The gentle movements may be beneficial in softening fibrous tissue across the chest and upper back. As in the case of yoga research for breast cancer, yoga may offer improvements in QOL and reduce pain, fatigue and the sensations associated with lymphoedema. Yoga, with its focus on mindful awareness, may aid in developing self-effectiveness which may, in turn, lead to an improved ability to deal with the effects of lymphoedema, both personally and socially.

Women with BCRL are already attending yoga classes, so it is essential that well-designed research into the effect of yoga on BCRL be implemented in order to establish its actual effectiveness. As women with BCRL will have had lymphoedema for varying lengths of time and diverse breast cancer treatments, there is also a need for the development of safe and appropriate guidelines for yoga teachers, who need to be informed about both secondary lymphoedema and the different effects of breast cancer treatment. As the effect of yoga on BCRL has not previously been researched, full consideration must be given to the integration of research findings from each of the areas discussed above to provide a safe and effective yoga practice, which considers each woman's overall health.

2.7 Conclusion

The reviewed literature has discussed the existing evidence and context of the relevant research covering breast cancer, BCRL and yoga. As such, it has informed the need for the current pilot trial, its context within the area of holistic physical therapy for women with BCRL, the development of a safe and effective yoga practice, and the choice of appropriate and validated measuring tools. The reviewed literature has been worldwide in its scope and has included varying designs and methods, both qualitative and quantitative. Studies included case studies, single-arm pilot trials with small sample sizes, RCTs of varying size, longitudinal studies with large sample sizes, systematic reviews and population-based census data.

Briefly, the reviewed literature has shown that, despite changes to the surgical and radiation treatment for breast cancer, at least 20% of the women will continue to be affected by BCRL and that as BCRL is life-long, women need to self-manage their symptoms to prevent the condition worsening and to prevent or reduce the occurrence of infection. While professional treatments, such as CLT, MLD and compression, are regularly used, lifestyle treatments, including exercise, have been shown to reduce symptoms and infection and improve aspects of physical function and QOL without causing or exacerbating lymphoedema. Such positive outcomes have also occurred in two small RCTs, one based on *tai-chi* and diaphragmatic breathing, and the other on gentle exercise and relaxation, which indicates that yoga too may be beneficial.

While there is a lack of research into the effect of yoga on BCRL, outcomes from other yoga research include improved QOL, physical function and immunity, as well as reduced pain and fatigue. This research comes from controlled and non-controlled yoga studies of women during or after breast cancer treatment, of people with other illnesses, and of specific practices such as breathing, meditation and relaxation. Further, the specific yoga practices used in the yoga therapy component of the holistic treatment plan for lower limb lymphoedema from filariasis in India can inform practices for BCRL.

Currently, there is no published research into the effect of yoga on BCRL and this review has shown that the need for such research is paramount, for the following reasons:

1. Some women with BCRL are already participating in yoga and searching for complementary therapies;
2. Women with BCRL may benefit from the kind of holistic treatment that yoga offers;
3. Beneficial and non-harmful effects have occurred in supervised exercise trials on women with BCRL, including positive outcomes from smaller yoga-type studies;
4. No guidelines exist for teaching yoga to women with BCRL.

The design and methods of the current trial are provided in the next chapter.

CHAPTER THREE METHODS

The methods used to conduct the pilot trial will be outlined in this chapter. A description is provided of the trial protocol, the yoga intervention, data analysis and the quantitative and qualitative outcome measures.

The aim of administering these measures was to obtain information about the safety and effectiveness of yoga for women with BCRL; this information does not currently exist. For this reason, a large number of measures were chosen to provide a broad view of the possible effect of the yoga intervention, which could inform future trials.

3.1 Hypothesis

The hypothesis of this study was:

An eight-week integrated yoga intervention, consisting of a weekly 90 minute teacher-led class and a 42 minute home-practice by DVD, will have a beneficial effect on women with BCRL, as indicated by reduced swelling of the affected arm, reduced tissue density, fewer symptoms of pain, fatigue and sensations and their limiting effects on daily activity, improved QOL and upper body functioning. Yoga will also have a beneficial personal effect, as defined by each woman's individual perceptions. The yoga DVD will provide an effective home-practice tool.

3.2 Trial protocol

3.2.1 Study design and setting

This study was an RCT on women with stage one BCRL, as defined by the International Society of Lymphology (2006) whereby lymphoedema is characterised by swelling that subsides with arm elevation and pitting of the affected area.

The study compared the results of a group which received an integrated yoga intervention to those of a control group which continued to follow current best practice in the self-management of lymphoedema from a manual given to all participants pre-randomisation. Participants in the control group did not receive the yoga intervention. The control group was however, invited to participate in the yoga at the completion of all measurements.

Measurements were conducted at baseline (week 0), after which participants were randomised to the yoga intervention or the control group. Further measurements were made at week 4 (mid-point), week 8 (on completion of the yoga) and at week 12 (four weeks after the intervention).

The trial was held in Community Health Centres in two cities, Hobart and Launceston (Tasmania). Both locations included intervention and control groups.

3.2.2 Ethical considerations

This trial involved measuring and teaching yoga to a medically compromised group of women ie those with lymphoedema from breast cancer treatment. Before commencing the current trial, approval was obtained from the University of Tasmania Social Sciences Human Research Ethics Committee (HREC) (H0011534), which required yearly progress reports and prompt notification of any adverse events. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12611000202965, http://www.anzctr.org.au/default.aspx). The trial was conducted in accordance with the values and principles of the National Health & Medical Research Council National Statement on Ethical Conduct in Human Research (2007) by following the guidelines for fairness and equity, gaining informed consent, freedom from coercion, risk and harm minimisation, beneficence and confidentiality. The researchers declared no conflict of interest and no financial interest in the trial. The entire trial was carried out with integrity and respect for the participants and sensitivity for their welfare, following legal and ethical requirements (National Health and Medical Research Council & Australian Vice Chancellors' Committee, 2007). All assessors were also trained in these requirements before the trial commenced.

Participants were recruited according to a fair and equitable process (full details are given in section 3.2.4). Informed consent and freedom from coercion were carefully considered by giving clear information in written and oral form (full details are given in 3.2.5). All potential participants were given a detailed information sheet outlining the purpose, methods, dates, possible benefits, and strategies for the minimisation and management of risk and harm – Appendix A. Written in clear, plain English, this sheet allowed potential participants to fully understand the level of commitment required and to make an informed decision whether to participate or not. (One participant, who had low literacy skills, was given a special session explaining the details in full after her baseline measurements). The voluntary nature of participation was emphasised, the individual's right to decline without giving a reason respected. It was also clearly stated that, should a participant decide to withdraw from the trial at any time, she would be free to do so without consequences and without the need to provide an explanation. Subsequent communications with the actual participants were also in plain language and gave them the opportunity to seek further information and clarification from the principal investigator.

The thoracic spine mobility tests necessitated the placement of nine translucent markers on the skin of the participant's back. It was felt that this might be invasive for some women

who had been treated for breast cancer and participation in this particular series of measurements was totally optional.

Measures for risk and harm minimisation were followed (National Health and Medical Research Council & Australian Vice Chancellors' Committee, 2007). All participants received an information manual, specifically developed for this trial, on the best current practice for the management of secondary lymphoedema, based on the guidelines of the Australasian Lymphology Association (2009) and the Lymphoedema Framework (2006). Risks of lymphoedema exacerbation were managed by following the guidelines set out by the National Lymphedema Network in its Position Statement on Risk Reduction Practices (2011). The participants were advised to continue with their usual treatment plan during the trial and to seek medical help in the case of an infection or a flare-up of lymphoedema. Participants were further advised that, should infection or flare-up occur, they could continue in the trial if they chose to but that their measurements would not be included in the results, as it would change their status with regard to the eligibility criteria.

Further, at baseline, medical information for each individual was collected so that appropriate modification could be made during the measurement sessions or in the yoga classes. Participants were also encouraged to raise concerns at the measurement sessions. Time was made available at every class for the discussion of any medical concerns resulting from the yoga. In addition, participants were advised that they could talk with a local breast care nurse or the Executive Officer of the UTAS Ethics Committee. Full contact details were provided.

The principles of beneficence (do good not harm) (National Health and Medical Research Council & Australian Vice Chancellors' Committee, 2007), were followed diligently in this trial, as this is the underlying philosophy of yoga. The medical information was collected to ensure each individual's medical conditions could be addressed. Further, baseline questionnaires were sent pre-baseline measurement so that women could fill them in at their leisure, as they were long. To ensure women were not fatigued during the measurement sessions, refreshments were available, and magazines were provided for women to read in a comfortable seat while waiting their turn. At measurement sessions, extra staff ensured any problems could be addressed immediately. All women were escorted to and from their cars during both the yoga and the measurement sessions. Occupational Health and Safety Guidelines from UTAS were adhered to; for example, the floor was kept clear of obstacles, all equipment was hygienically cleaned between measurements and space was provided for bags, coats etc. UTAS insurance, which covered public indemnity and medical negligence, was sent to the venues where measurements and yoga were held. Participants were also offered a debriefing session at the completion of the trial.

Anonymity and confidentiality were ensured in this trial. Participants were assured that all personal information they provided (in questionnaires, interviews, logbooks and from the measurements) would be held in strict confidence and nothing disclosed without their permission. Access to this data would be restricted to the principal investigator. Participants' names would be coded in such a way that no individual would be identifiable from the information given. Anonymity was also pledged in any presentations or publications arising from the trial. No names or photos would be used without the permission of the participant(s).

During the period of the trial, paper-based data was stored in a locked filing cabinet in the Department of Rural Health's CML building in Hobart and other information for analysis kept on a password-protected computer. On completion of the trial, data will be securely stored for five years then destroyed, as required by the UTAS Ethics Committee.

3.2.3 Withdrawal from the study

Participants were able to withdraw from the study at any time without prejudice, as set out in the information sheet distributed to all participants.

3.2.4 Identification of eligible participants

Recruitment occurred over a two-month period throughout Tasmania. Key people, including professionals in the field of lymphoedema, and relevant organisations such as the Cancer Council and Breast Screen, and support and exercise groups such as Encore and Dragons Abreast, were contacted and asked to disseminate information about the trial to potential participants, through flyers and posters.

Media exposure was sought and resulted in articles about the trial in local newspapers and interviews on local ABC radio at both locations. Posters were put in major and rural hospitals, Women's Health Centres, Community Centres and on community noticeboards.

Individuals interested in participating were asked to contact the principal investigator (AL) who, after ascertaining if they were suitable for participation as per the inclusion and exclusion criteria, outlined the study, including the yoga intervention, the home-practice, the methods and dates of measurement. Eligible individuals were then sent an information sheet and informed consent form. After receiving the forms, they were contacted by telephone in order to discuss any questions or concerns about the trial before returning the signed consent form to the principal investigator. The information sheet is provided as Appendix A.

After the signed consent form was returned, participants were sent the dates for the trial (measurements and intervention) as well as questionnaires with demographic and medical information to be completed and brought to the baseline measurement. At this time, the manual for current best practice was also sent, and followed by another phone call to check

for clarity. One participant, who had low literacy skills, was given a special session explaining the details in full, and provided with assistance to fill in the baseline questionnaires.

3.2.5 Participants

Eligibility criteria based on previous exercise trials on women with BCRL were followed (Johansson, et al., 2005; Moseley, et al., 2005). Criteria for inclusion were completion of treatment for breast cancer in terms of surgery, radiotherapy and chemotherapy at least six months previously; unilateral secondary lymphoedema related to surgery for breast cancer stage one, as confirmed by a registered lymphoedema therapist; aged>18 years; and good English comprehension in order to understand the written forms and oral instructions and be able to give informed consent.

Criteria for exclusion were conditions of primary lymphoedema, recurrent cancer and other symptoms including infection or cellulitis, which would affect the woman's lymphoedema and her QOL adversely; severe psychological illness, as the yoga intervention would need to be specific to the person's psychological illness in order to improve it; pregnant women and women with pacemakers, as these conditions are contra-indicated for the use of BIS (Czerniec, et al., 2010); and current lymphoedema treatment other than self-management, as this would affect the results.

If there was doubt regarding the woman's lymphoedema status, her lymphoedema therapist was contacted to confirm that the woman had lymphoedema, as no resources were available to pre-test women.

Participants were also asked to refrain from commencing any **new** physical activity during the term of the trial, as this could affect results.

3.2.6 Randomisation

A third party not associated with the trial performed the randomisation based on a computer-generated random number system after informed consent. Group notification in a sealed envelope was given to participants after completion of the baseline measurements.

3.2.7 Sample size calculation

An a priori sample size calculation based on clinically significant changes between groups of between 10-20% in the primary outcome measures of arm volume of lymphoedema and L-dex reading with standard deviations (SDs) of between 12 and 15% of the mean, or within groups 10% difference with an SD of 20%, indicated that numbers of between 13 and 19 participants would be required per group. Consequently, it was planned to recruit 20 participants per group to allow for a small number of withdrawals.

3.2.8 Data analysis

Medical and demographic information was analysed using descriptive analysis within SPSS (version 19; IBM, Armonk, New York, USA) to calculate means and SDs or percentage values. Differences between groups were assessed using independent two-tailed t-tests for comparing continuous variables and Yates corrected chi-square tests for categorical variables.

All other statistical analyses were performed using STATA statistical software (version 12; STATA Corporation, College Station, Texas, USA). Parametric longitudinal data was analysed via mixed methods linear regression. Non-parametric data was analysed via ordinal logistic regression. Post-hoc testing was performed on both parametric and non-parametric data using the Holms test to locate the means that were significantly different. Statistical significance was set at $p<0.05$.

The yoga lesson and DVD were formulated and taught by the principal investigator as she was qualified, accredited and experienced in both yoga therapy and MLD. Nevertheless she did not perform the outcome measures, and as information was coded for the statistical analysis, the data could not be identified and manipulated.

Interviews were analysed using an iterative-thematic approach. Full details are given in 3.5.

3.2.9 Outcome measures at baseline and weeks 4, 8 and 12.

All assessors were trained pre-trial in specific measures, using standardised protocol and validated instruments. Moreover, they all had a practice measurement session with four women with BCRL who were not part of the trial. Two qualified lymphoedema therapists took the lymphoedema measurements, one in Hobart, one in Launceston. Other assessors were fourth- year Human Life Sciences students, physiotherapists and a professional oncology massage therapist. They worked in pairs and performed the same measure at both locations, one person taking the score and the other recording it. All assessors were blinded to group allocation and to previous scores. Each measure was performed by the same assessor at each time-point.

Participants were advised to abstain from alcohol for 12 hours prior to each measurement session, and from caffeine and heavy exercise for two hours before. Each participant was allocated a specific time and day that did not change during the trial in order to ensure consistency. One participant had to change her time due to changed childcare arrangements, and this may have had an impact on her L-dex results.

Lymphoedema was measured in the same order each time: BIS, circumferential scores, then tonometry. ROM of shoulder was followed by grip strength and measured by the same

assessors. Strength of shoulder and separate muscles were measured in that order by other assessors. Another assessor recorded height and weight and administered the questionnaires, which included the collection of baseline demographic and medical information.

Measurements for the thoracic spine sub-group were held the day after the other measurements at baseline, weeks 8 and 12 by trained Human Life Sciences students. The interviews for the intervention participants were conducted at week 8 by an experienced professional trained in interview techniques.

All equipment was calibrated prior to each measurement session. All data was recorded onto a case record form for each participant, then transcribed into a specifically designed trial database. The interviews were recorded and transcribed into documents. All data was stored on a password-protected computer.

The medical questionnaire and samples of the forms used for recording of measurement of lymphoedema levels, ROM and grip strength, and spinal mobility appear in Appendix B.

3.2.10 Intervention compliance

A protocol was established for the intervention group in the event of absence from a class, so that another class could be organised when possible. Attendance at the yoga class was recorded weekly and DVD compliance self-recorded in a logbook collected at weeks 4 and 8.

Outcome measures at measurement sessions are illustrated in Table 3.1.

Table 3.1 *Outcome Measures at Baseline, Weeks 4, 8, 12.*

Baseline (week 0) Measurements	**Week 4 Measurements-after 4 weeks intervention**	**Week 8 Measurements-at completion of intervention**	**Week 12 Follow-up Measurements**
Collection of medical and demographic questionnaires		Intervention group: interviews	
Logbooks of daily yoga practice to intervention group	Collection of logbooks	Collection of logbooks	
Lymph measures: • BIS • Circumference • Tonometer • VAS symptoms	Lymph measures: • BIS • Circumference • Tonometer • VAS symptoms	Lymph measures: • BIS • Circumference • Tonometer • VAS symptoms	Lymph measures: • BIS • Circumference • Tonometer • VAS symptoms
Weight/height BMI	Weight/BMI	Weight/BMI	Weight/BMI
QOL: LYMQOL questionnaire	QOL: LYMQOL questionnaire	QOL: LYMQOL questionnaire	QOL: LYMQOL questionnaire
Arm measures - strength: • Shoulder • Sep muscles • Grip Arm measures - ROM • Shoulder	Arm measures - strength: • Shoulder • Sep muscles • Grip Arm measures - ROM • Shoulder	Arm measures - strength: • Shoulder • Sep muscles • Grip Arm measures - ROM • Shoulder	Arm measures - strength: • Shoulder • Sep muscles • Grip Arm measures - ROM • Shoulder
Physical activity: • IPAQ –short form (weekly) • VAS (daily)	Physical activity: • IPAQ –short form (weekly) • VAS (daily)	Physical activity: • IPAQ –short form (weekly) • VAS (daily)	Physical activity: • IPAQ –short form (weekly) • VAS (daily)
Thoracic spine – sub group: • Spinal ROM video		Thoracic spine – sub group: • Spinal ROM video	Thoracic spine – sub group: • Spinal ROM video

3.3 The Yoga Intervention

The yoga intervention consisted of a weekly 90-minute yoga class for eight weeks taught by the same qualified, accredited and experienced yoga teacher at both locations. Participants were also given a specially made 42-minute DVD containing a shorter version of the class, and instructed to perform it daily. The home-practice DVD is attached as

Attachment 1. Participants were given a logbook in which to record their home sessions and make relevant comments.

Systematised yoga practices and instruction approaches were based on the Satyananda Yoga® style of teaching (Saraswati, 1996). This style, with its gentle repetitions of physical movements followed by rests, and use of modifications, was considered to be well-suited to women with BCRL.

Each yoga class had an appropriate warm-up and cool-down, following the exercise guidelines for women with BCRL (National Lymphedema Network, 2011b; Schmitz, Ahmed, et al., 2009). The temperature of the room was controlled to between 19 and 22 degrees Celsius (suitable for Tasmania). The decision to wear or not wear a compression sleeve was made by the individual as long as it was worn again after the class (Johansson, et al., 2005). Participants were advised to wear bras with wide straps to avoid extra pressure on their shoulder that could worsen swelling from lymphoedema (Carati, et al., 2009). Participants' other health requirements were also considered.

The integrated yoga intervention consisted of slow, deep breathing, a series of moving yoga postures followed by rests, a held standing balance, *pranayama* (*nadi shodan*), meditation based on mindfulness practices and candle meditation, and deep relaxation with arm elevation. Each class was followed by a group discussion. The practices were chosen to promote lymphatic clearing, improve upper body functioning and reduce stress. Each practice was informed by research from the areas of lymphoedema, exercise for women with BCRL, yoga, yoga for breast cancer and yoga therapy for people with lower limb lymphoedema. The full yoga class is described in Appendix C.

Options for modifications enabled an individualised approach based on comfort, needs and preferences, in both the class and home-practice DVD. This was exemplified in the DVD, in which two women each demonstrated a different version of the physical practices, such as one lying on a mat and the other sitting in a chair. Practices were progressive for each component of the yoga intervention. For example, the mindfulness techniques progressed from witnessing sensations (*antar mouna* 1) to witnessing thoughts (*antar mouna* 2); the *yoga nidra* relaxation introduced an added stage at week 5 (awareness of opposites); and a focussed candle meditation (*tratak*) was included at weeks 7 and 8. Similarly, extra postures were given which were a little more difficult, as was appropriate. Finally, the group discussion at the end of each class progressed from general themes to the ways in which yoga could be incorporated into participants' lives after the intervention ceased.

3.4 Primary and secondary outcomes

3.4.1 Characteristics of the sample

Participants brought completed demographic and medical questionnaires to the baseline measurements. This questionnaire appears in Appendix B. These were collected and data entered into a specifically designed trial database.

3.4.2 Primary outcome measures

3.4.2.1 Lymphoedema

All lymphoedema measurements were conducted with the participant resting in a supine position, with her compression sleeve removed. The dominant and affected arms were noted as this information is needed for the calculation of L-dex scores and arm volume calculations. Weight and height were measured on the same equipment each time in order to calculate BMI. The reporting form for lymphoedema and tonometry measures appears in Appendix B.

i Extra-cellular fluid

Extra-cellular fluid was measured according to the protocol of Czerniec et al. (2010), using bioimpedance L-dex™ XCA (ImpediMed, Brisbane, Queensland, Australia), with electrodes placed at anatomical landmarks at the wrist of each arm and right ankle. It has high inter-rater reliability (Ward, 2009). An increase in extra-cellular fluid is paralleled by a decrease in impedance from the low-frequency electrical current. The result is recorded as a ratio to the non-affected limb, taking into account arm dominance. As lymphoedema increases, so does the ratio of impedance (Cornish, et al., 1996; Rockson, 2007). The result, calculated from software provided by Bio-Impedimed, was recorded as an L-dex score. Any score equal to or higher than 10 is considered an indication of clinically manifest lymphoedema.

ii Volume of arm and hand lymphoedema

Circumferential readings were based on the protocol of the Australasian Lymphology Association (Koelmeyer, Shanley, Reul-Hirch, & Piller, 2004), modified so that the participant was lying, not sitting. Both arms were marked at the metacarpophalangeal joint, ulnar styloid and 10, 20, 30, 40 centimetres (cm) from the styloid process, using a pen and set square on the medial and lateral aspect of the arm, then the circumference measured at each point by a Job non-stretch tape, recorded in cm. Finger circumferences were measured distal to the web space, and recorded in millimetres (mm). Volumes of arm and hand lymphoedema were calculated using the truncated cone formula (Stanton, Badger, & Sitzia, 2000) from the addition of circumference readings, using software provided by Flinders Lymphoedema Clinic, S.A., which compares the affected with the non-affected arm. An increase in fluid

volume scores equated to an increase in lymphoedema. Fluid volume was recorded as millilitres (ml).

3.4.2.2 Density of fibrous tissue

Density of fibrous tissue was measured by a digital tonometer, model 1383 (Bio-medical Engineering, Flinders Medical Centre, S.A.), validated specially for this population (Bates, Levick, & Mortimer, 1994; Clodius, Deak, & Piller, 1976), following validated protocol (Moseley & Piller, 2007b). Tonometry measurements were taken on the forearm 10 cm from the cubital fossa and on the upper arm 10 cm up from the cubital fossa in the middle of the lymph territory. Additional measurements were taken at the anterior trunk at the mid-clavicular line between the second and third ribs and the posterior trunk between the acromion and the first thoracic rib in the subscapular fossa. The digital tonometer measures the resistance of the tissues to compression, i.e. the amount of fibrotic induration (collagen build-up) in the superficial tissues at a given point (Piller, 2007; Stanton, et al., 2000). Each measurement was followed by a three-second pause before remeasuring. A higher score, recorded in mm, denoted a higher level of tissue density. The average of three scores was recorded.

3.4.2.3 Physical sensations associated with lymphoedema

Visual Analogue Scales (VAS) have been validated as an effective method of recording individual perceptions of subjective domains such as pain (Harms-Ringdahl, et al., 1986), and adapted in lymphoedema trials to include sensations specific to lymphoedema (Jahr, et al., 2008; Johansson, et al., 2005).

A VAS scale developed specifically for the current trial was used to measure the severity of the lymphoedema sensations which each participant identified, such as heaviness, tingling, aching. The VAS scale also measured pain and fatigue, and the degree to which sensations, pain and fatigue had limited participants' activity on the day of measurement. The scale was scored as 0cm being 'no discomfort' and 10cm being 'the worst imaginable'.

3.4.2.4 Quality of life

A validated questionnaire, developed specifically to measure QOL in people with lymphoedema (LYMQOL), was used (Keeley, et al., 2010). Its upper limb version was used in the current trial. Total QOL score was between 0-10, 10 being the best and zero the worst. The score recorded was the number the participant self-reported. A higher score denoted a higher total QOL. Sub-scales for function, symptoms, appearance and emotions were also included in the questionnaire. Each of these included several questions which are marked from 1 to 4, four being the worst. The sum of answers in each sub-scale of function, symptoms, appearance and emotions was calculated, then divided by the number of questions in that sub-scale to give a score for each sub-scale. A higher score denoted a lower QOL associated with that sub-scale.

3.4.3 Secondary outcomes measures

3.4.3.1 Range of motion of the shoulder (ROM)

The ROM of the shoulder of the non-affected, then the affected, arm was measured using a goniometer which has been validated for clinical trials (Riddle, Rothstein, & Lamb, 1987) and used in trials on women with BCRL (Box, et al., 2002b; Todd, et al., 2008). An established protocol (Box, et al., 2002b) was followed. Participants sat in a low-back chair with stable shoulder blades and suitable back support, their knees bent to 90° and their feet at hip width and flat on the floor. Flexion, abduction and extension of the shoulder in the sagittal or coronal planes were measured from the starting point of arms in anatomical position. Internal and external rotation of the shoulder were measured from the starting position of the arm abducted to 90°, forearm pronated and parallel to the floor, palm down, with elbow bent to 90°. To prevent fatigue, measuring was conducted in the following order: flexion, internal rotation, extension, abduction, external rotation. The endpoint of measurement was full range, compensatory movements of the shoulder or trunk occurring, or participant experiencing pain or tightness. The final score was recorded in degrees as the best of three attempts. The higher the score, the greater the range of motion. Reporting form appears in Appendix B.

3.4.3.2 Grip strength

Hand grip strength was measured by a hand-held grip dynamometer (Smedley, Stoelting Company, Wood Dale, Illinois, USA), which has been validated for use in a clinical setting (Bohannon, 2005), and followed a protocol used in lymphoedema trials (Johansson, et al., 2001). The participant sat in a stable position with her elbow bent to 90° and close to her body, palm facing inwards. Grip strength was measured by applying pressure to the dynamometer with the non-affected, then the affected, hand. Measurement ceased at full strength or if pain or instability occurred. The best of three attempts was recorded in kilograms (kg). A higher score denoted a greater grip strength.

3.4.3.3 Strength of the shoulder and separate muscles

Muscle strength was assessed using a Commander Powertrack II Muscle Tester (JTechMedical, Salt Lake City, Utah, USA), validated in a healthy population (Leggin, Neuman, Ianotti, Williams, & Thompson, 1996) and used and recommended in lymphoedema trials (Dawes, et al., 2008; Johansson, et al., 2001; Lee, et al., 2008), and followed an established protocol for muscle testing (Kendall, et al., 2005). The participant sat in a stable position and the non-affected, then the affected, arm was measured in turn, three times for each action. The arm was raised to 90° for the strength measurement in flexion, horizontal adduction and abduction. To measure the strength in extension, the participant's arm was by her side. The arm was positioned slightly across the body for the strength measurement of the pectoralis major and the arm elevated to 120° for the serratus anterior. The strength of

pectoralis minor was measured with the participant in supine position. This was also the order of measuring used to prevent fatigue.

The strength of the shoulder/separate muscles was measured from the force applied against the resisted hand-held dynamometer, held by the assessor, for a count of three seconds. Measurement ceased when full strength was applied, compensatory movements of the shoulder or trunk occurred or pain was experienced. The best of three attempts was recorded in newtons (n). A higher score denoted a stronger muscle action.

3.4.3.4 Thoracic spine mobility

Thoracic spine mobility was measured dynamically using video analysis in order to quantify the functional mobility of the spine during lateral flexion, flexion/extension and thoracic spinal rotation, and followed a validated protocol (Menegoni, Vismara, Capodaglio, Crivellini, & Galli, 2008). Spinal ROM was recorded by a video camera with backlighting, utilising reflective surface markers placed on participants' skin at the following locations: left and right posterior superior iliac spines (LPSI, RPSI), spinal processes (S1, L3, L1, T6, T1) and left and right acromion (LACR, RACR). As the use of video analysis with surface markers applied to the skin may be invasive for women who have been treated for breast cancer, participation in this trial was voluntary.

Reflective markers were also placed on the wall behind, or on the floor around the chair in the case of rotation, to provide calibration references. At the initial measurements, the distance between markers applied to the participant's skin was taken and recorded on her data sheet, to ensure consistency at each following measurement.

Participants were measured standing, starting from a stable anatomical position, in lateral flexion and flexion/extension, with the camera at a distance of two metres behind them (lateral flexion) or side on to them (flexion/extension), and in stable sitting position in thoracic spinal rotation with the camera one metre overhead. Participants were given a demonstration of each movement and then practised each movement before being filmed. For lateral flexion, participants were instructed to slide their little finger down one side of their leg then return to starting position, before repeating on the other side, without twisting. For flexion/extension, they were instructed to bend or relax their knees slightly, contract their abdominal muscles, keep their chin tucked in, keep their arms by their sides and flex forwards, return to starting position, then extend backwards, and return to starting position. For thoracic spinal rotation, they were instructed to keep their hips and legs stable and rotate from their waist, one way, then back to starting position, then in the other direction and back to starting position. Each movement was performed three times, stopping at the point of full range, instability or pain. The form used for recording this measure appears in Appendix B.

Video footage was downloaded and stored on a password-protected computer at the end of each measurement session. Video data was then analysed using Quintic™ Sports Biomechanics Video Analysis Software (9.03 version 14; Quintic Consultancy Limited; www.quintic.com). Measurements were made of the position of each marker in the reference plane from resting position to range in each direction. This allowed calculation of the angles in degrees, from software specifically made for this trial (Human Life Sciences, UTAS), following the calculated measures described in another trial (Menegoni, et al., 2008).

For some measures, such as in pelvic obliquity and angle of kyphosis, a reduction was an improvement. Other scores were dependent on the movement pattern in comparison to other areas of the spine, so an increase could sometimes be an improvement and sometimes be a deficit.

The angles measured for lateral flexion in the frontal plane are presented in Table 3.2 and illustrated graphically in *Figure 3.1*. Pelvic obliquity (β1) is a static angle. The other measurements are the range in each direction, added to give the full range.

Table 3.2 *Definition of Spinal Angles Measured for Lateral Flexion.*

Abbreviation	Action lateral flexion	Definition
β1	Pelvic obliquity at rest	The angle between the pelvic axis and the horizontal plane.
β2	Lumbar range	The angle of projection between the S1-L1 vector and the vertical pelvic axis.
β3	Thoracic range	The angle of projection between the T1-L1 vector and the S1-L1 vector.
β4	Shoulder range	The angle of projection of the vector connecting both shoulders with the horizontal plane.
Bdc	Thoracic distal curvature range	The angle of projection between vectors S1-L3 and L3-T6.
Bpc	Thoracic proximal curvature range	The angle of projection between vectors L3-T6 and T6-T1.
Blti	Full lateral trunk inclination range	The angle between the projection of the S1-T1 vector and the vertical axis.

(Menegoni, et al., 2008, p. 180)

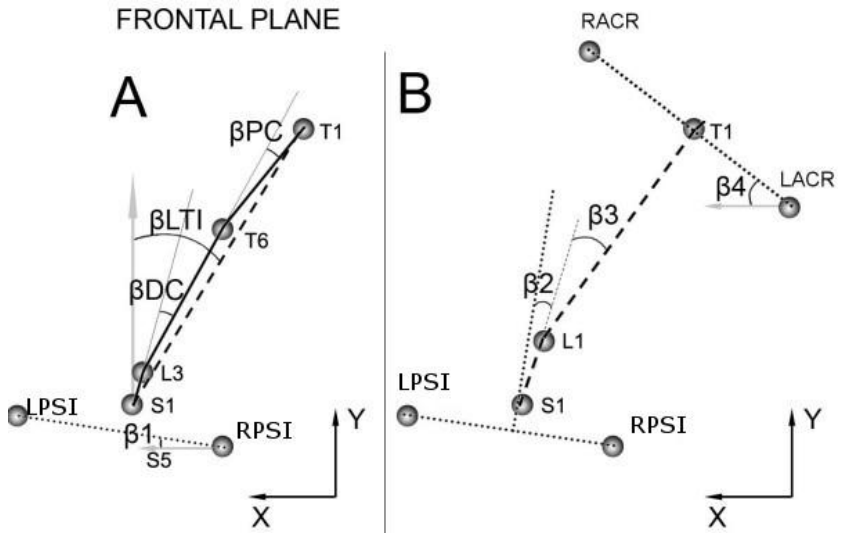

Figure 3.1 Representation of markers and angles in the frontal plane for lateral flexion**.**

LPSI left posterior superior iliac spine
RPSI right posterior superior iliac spine
RACR right acromion
LACR left acromion
(Menegoni, et al., 2008, p. 180)

The angles measured for flexion/extension in the sagittal plane are presented in Table 3.3 and illustrated graphically in *Figure 3.2*. The angle of thoracic kyphosis at rest (**αkrest**) is a static angle. The other measurements are the range in each direction, added to give the full range.

Table 3.3 *Definition of Spinal Angles Measured for Flexion/Extension.*

Abbreviation	Action Flexion/extension	Definition
α3	Thoracic range	The angle between the projection of the T1-L1 vector and the S1-L1 vector through the full range of flexion/extension.
αkrest	Angle of thoracic kyphosis at rest	The angle between the vectors L3-T6 and T6-T1.
αfti	Full trunk flexion/extension range	The angle between the projection of the S1-T1 vector and the vertical axis in flexion/extension.

(Menegoni, et al., 2008 p 180)

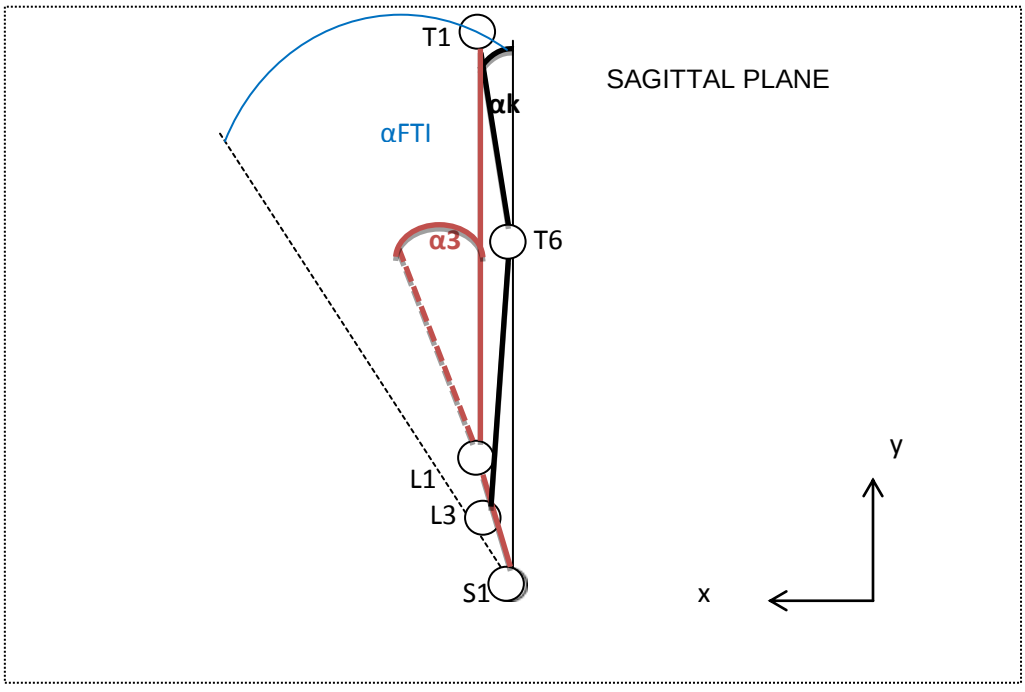

Figure 3.2 Representation of markers and angles in the sagittal plane for flexion/extension.

The angle measured for thoracic spinal rotation (Tr) in the transverse plane is presented in Table 3.4 and illustrated graphically in *Figure 3.3*. The range is measured in each direction, then added to give the full range.

Table 3.4 *Definition of Spinal Angles Measured for Thoracic Spinal Rotation.*

Abbreviation	Action Thoracic rotation	Definition
Tr	Thoracic spinal rotation range	The angle between the projection of the vector from the line of the shoulders and the vector defined by the line of the hips throughout the full range of thoracic spinal rotation.

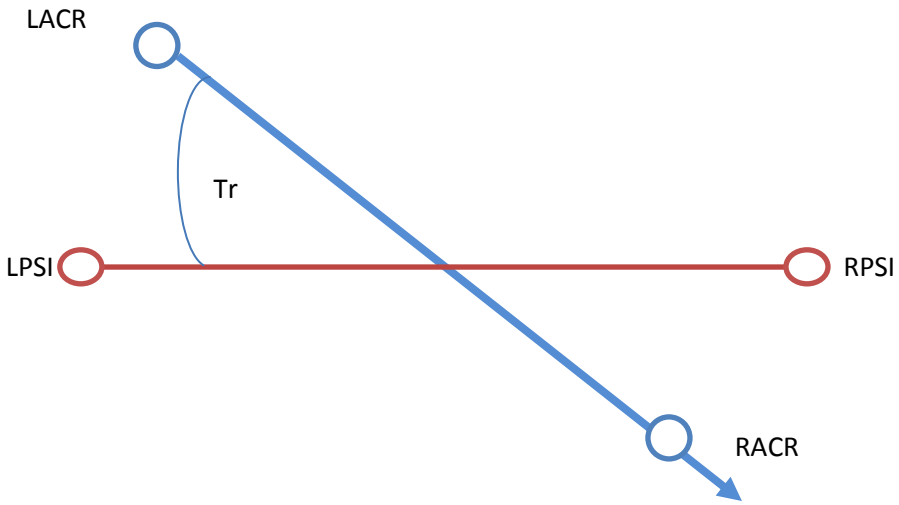

Figure 3.3 Representation of markers and angle in the transverse plane for spinal rotation.

LPSI left posterior superior iliac spine
RPSI right posterior superior iliac spine
RACR right acromion
LACR left acromion

3.4.3.5 Physical activity

Physical activity was recorded at each measurement due to its possible impact on other outcomes such as lymphoedema, sensations, pain, fatigue and shoulder actions. Physical activity for the week prior to each measurement was reported using the IPAQ short form, proven reliable in the PAL trial (Schmitz, Troxel, et al., 2009). The questionnaire measures the amount of vigorous, moderate and walking activity in intensity and duration, as well as the number of minutes in sitting. The total time in each activity is multiplied by an intensity value to calculate total weekly activity reported in $MET.min^{-1}$. The total $MET.min^{-1}$ score is also given a value of 1=light; 2=moderate; 3=high. Sitting time is recorded as the total number of minutes for that week.

Physical activity for the day of measurement was recorded on the VAS scale as a number from 0-10, with zero indicating no activity and 10 indicating constant activity.

3.5 Interview for participants in the yoga intervention

A 20-minute audio-taped interview, conducted by an independent and experienced interviewer, was held at week 8 for the participants in the yoga intervention. Questions were open-ended in relation to the yoga classes and DVD as follows:

How has this study being going for you (ie from your perspective)?

Can you talk to me about how the yoga has helped you or been difficult for you?

Are there any particular aspects of the actual yoga class that you'd like to discuss?

What about the daily home-practice DVD?

How did you stay motivated?

Can you suggest any changes or improvements that could be made?

Do you have anything else you'd like to say or add?

Relevant comments were explored further by appropriate prompting (e.g. "So you said your posture improved; can you tell me how exactly?") As specific information was sought about the effectiveness of the yoga class and the DVD, the interviewer prompted women to voice their opinions about possible improvements.

The recorded interviews were listened to several times in order to gain a general understanding, then transcribed verbatim into Word documents. Specific features, such as moments of laughter, hesitation, silence and emphasis, were noted in the transcripts.

Data analysis was by an iterative-thematic approach focussing on the actual words and their frequency within each interview. This focus is a form of data validation (Cavanagh, 1997). As no literature currently exists on the effect of yoga on women with BCRL, an inductive method was used to group words and content from the specific to larger, more general groupings of content (Elo & Kyngas, 2008). Two researchers worked independently which validated the data reproducibility (Cavanagh, 1997). Each noted in the margins of the text a word or phrase representing each idea expressed in the interview. These were then grouped together so that comparisons could be made between the interviews. At their first meeting, the researchers compared annotations and groupings, and after resolving points of discrepancy, agreed upon the following broad themes: Physical, Mental, Social, The Yoga Class and DVD and The Breast Cancer Experience. A numerical code (1-5) was assigned to these themes in the order mentioned. This resulted in similar content from each interview being listed into each theme.

Then, the two researchers, worked independently once more and proceeded to a systematic classification of the text data into content-related sub-themes sharing the same essential meaning (Fu & Rosedale, 2009; Williams, Moffatt, & Franks, 2004). These sub-themes were temporarily located within one of the five themes and assigned a letter code (e.g. 1A, 2D, 3C). When smaller themes appeared in the sub-themes, further codes were given (e.g. 4A1) and when necessary, a final code representing a smaller division in the sub-theme was given (e.g. 4A1i). For example, 4A1ii refers to comments about the breathing section (ii) of the practical session (1) of the yoga class (A) in the theme of The Yoga Phenomenon (4). The researchers met again to compare and collate their analyses, test their individual interpretations and resolve any discrepancies. At this stage, some sub-themes were deleted, some moved from one theme to another and some redefined.

Some sub-themes were difficult to classify; for example, Time for Self could have been included in either Mental Health Outcomes or Social Outcomes, while Group Dynamic could have been viewed as a sub-theme of either The Yoga Phenomenon or Social Outcomes. A final decision was made based on the overall context in which the ideas were expressed. As the thematic analysis progressed, it became obvious to both researchers that many participants had made an extraordinary 'journey' during the yoga intervention. It was decided, therefore, to create a sixth theme (Individual Journeys).

In this way, themes, sub-themes and codes were definitively established. By systematising participants' comments into quintessential, recurrent themes, while staying close to the text data, a comprehensive picture of how each participant had perceived and experienced the yoga intervention emerged.

The third and final analysis of the text data had three principal goals: (1) to identify which narratives should be included in theme 6 (Individual Journeys); (2) to note particularly compelling pieces of text which illustrated the participant's experience with the maximum of evidence for each sub-theme; and (3) to assess the frequency of textual statement within each sub-theme as supportive evidence.

Upon completion of this analysis, the two researchers independently scrutinised the participants' two logbooks in order to extract all entries pertaining to the themes and sub-themes already identified, while remaining open to the possibility of new themes/sub-themes. At their final meeting, they examined all the information that they had collected separately during these last two procedures. Neither had identified any further themes/sub-themes in the logbooks and agreement was reached on where and how to incorporate the material gleaned from the logbooks. They slightly changed the names of the themes to describe more fully the results, i.e. Physical Outcomes, Mental Health Outcomes, Social Outcomes, The Yoga Phenomenon, The Breast Cancer Experience and Individual Journeys. They decided to include in full nine Individual Journeys. They agreed which particularly cogent passages could later be used as supportive quotations during the discussion of the results. They recorded the total number of respondents and responses for each sub-theme. This list is presented in Appendix D.

3.6 Conclusion

This pilot trial was designed to determine the objective and subjective effects of a yoga intervention on the lymphoedema and its sequelae, QOL and upper body functioning of women with BCRL and to gauge the perceived effectiveness of the home-practice DVD. It was hypothesised that yoga would offer another safe, self-management option for women with BCRL.

As no previous published yoga study existed, great care was taken with the organisation of the trial and the yoga intervention. Validated measures were chosen that had been used in other exercise trials for women with BCRL. Assessors were chosen who were experienced in their field, and who also underwent pre-trial training. Processes, forms and methods of storing records were refined prior to the trial. Post-measurement meetings with staff were held during the trial to clarify and rectify any problems that may have occurred.

Information provided to the participants was pre-checked for clarity and reminders of measurement times were sent throughout the trial. Women's safety was reinforced during the yoga sessions, in the DVD and at all measurement sessions. The yoga session was developed from positive research findings from the fields of breast cancer, BCRL and yoga, with the utmost care taken to avoid exacerbation of lymphoedema and its sequelae.

Outcomes are presented in the next two chapters. Chapter 4 will present quantitative results and Chapter 5 will present qualitative results.

CHAPTER FOUR RESULTS 1

This chapter will present the participation and attendance rates, demographic and medical characteristics of the sample, followed by the results for the primary and secondary objectives in the control (con) and intervention (int) groups. A sample of individual results showing the association between subjective (reported in Chapter 5, Results 2) and objective results will also be presented.

Results will be reported from baseline to week 8 (b-8) and from weeks 8 to12 (8b-12). Due to attrition, there were fewer participants for the 8b-12 period. Statistically significant changes ($p<0.05$) between and within groups over the intervention period will be reported. Some trend data will also be reported where appropriate. Full results for primary and secondary outcomes and physical activity will be presented in tables for each measure. Between group results will report mean difference (md), 95% Confidence Intervals (CI) and p values. Within group results will report group means (m) with standard deviations (SD) and p values.

All women in the current trial had been diagnosed clinically with lymphoedema, using standardised testing and equipment available to professional lymphoedema therapists in Tasmania and based on guidelines of the Australasian Lymphology Association (Australasian Lymphology Association, 2009). However, when tested with bioimpedance (BIS) hired specially for this study, only eight women had a baseline L-dex score>10, which is regarded by some researchers as an indication of lymphoedema. For this reason, results of this sub-group were also analysed. However, as results of this sub-group reflected the results of the group as a whole, only significant $p<0.05$ between group results will be given. Full results for the L-dex>10 sub-group appear in Appendix E.

4.1 Characteristics of the sample

4.1.1 Participation in the trial

A total of 59 women applied to take part. Of these, 13 were ineligible and a further 18 declined participation for various reasons related to health, holidays and work.

At baseline, 28 women took part in measurements. Before the first week of the yoga intervention, one woman in the intervention group was diagnosed with cellulitis. At week 4, two women in the control group were unable to be measured, as one had cellulitis and one had to withdraw from the study as her daughter was hospitalised and she became the chief carer of her grandchild. At week 5, one woman in the intervention group was hospitalised for surgery and at week 8, after the completion of the yoga, one woman in the intervention group fell and broke her hip and was not able to take part in the week 8 measurements.

Shortly before the week 12 measurements, two women were diagnosed with secondary breast cancer (one in the intervention group and one in the control group), one woman in the intervention group went overseas and another woman in the intervention group had cellulitis.

This meant that the measurements of 23 women could be considered from b-8, and 19 women could be considered from 8b-12. Participant flow through the trial, including reasons for withdrawal, is shown in *Figure 4.1*.

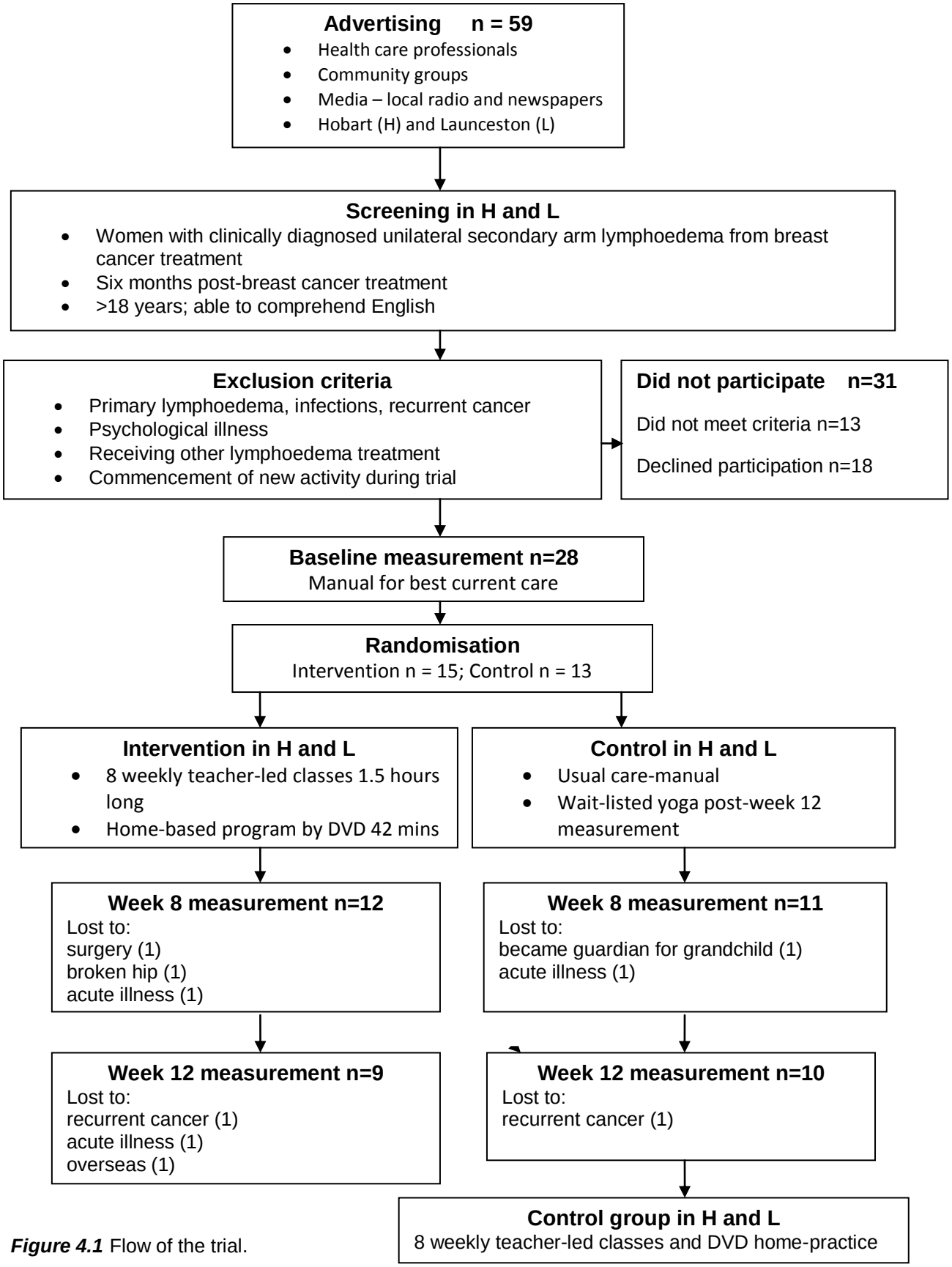

Figure 4.1 Flow of the trial.

4.1.2 Personal and social demographic characteristics

Twenty-three participants, with a mean age of 57.6 ±10.5 years (range 34-80) and a mean BMI of 27.2±4.9 kg (range 20.4-37.3), completed the eight week intervention and 19 women returned for the week 12 follow up measurement. No women were doing yoga during the trial, nor had they done it since developing BCRL.

There were two significant between group differences for personal and social characteristics at baseline. The BMI of the intervention group was significantly higher than that of the control group (md=4.03; CI=0.24; 7.81; p=0.023). A greater number of women in the control group attended group exercise (including the gym) than in the intervention group (p=0.006). Women in the control group were also more actively involved in organisations (p=0.09) and physical hobbies (p=0.094) than the intervention group. Other characteristics of the personal and social demographic were evenly distributed and are illustrated in Table 4.1.

Table 4.1 *Personal and Social Demographic Characteristics.*

Characteristic	Intervention (n=12)	Control (n=11)	P value[a]
Hobart %	8 (66.7)	8 (72.7)	
Launceston %	4 (33.3)	3 (27.3)	
Age years			
Mean ± standard deviation(SD)	55.1±2.5	60.5±3.6	0.230
Range	36 –65	34-80	
BMI			
Mean + SD	29.1±4.63	25.1±4.45	**0.023**
	n %	**n %**	**P value[b]**
Country of Birth			
Australia	7 (58.3)	9 (81.8)	
England	3 (25)	2 (18.2)	0.740
Other (Canada, Italy)	2 (16.7)	0	
Education			
Primary	1 (8.3)	1 (9.1)	
High school	1 (8.3)	1 (9.1)	
Tertiary	5 (41.7)	2 (18.2)	0.801
Graduate	3 (25)	5 (45.5)	
Post graduate	2 (16.7)	2 (18.2)	
Living arrangements			
Live alone	2 (16.7)	3 (27.3)	0.912
Live with others	10 (83.3)	8 (72.7)	
Occupation %			
Home, retired	5 (41.7)	8 (72.7)	0.280
Employed	7 (58.3)	3 (27.3)	
Fitness (self-scored) %			
Low	2 (16.7)	1 (9.1)	
Medium	8 (66.7)	8 (72.7)	0.913
High	2 (16.7)	2 (18.2)	
Member of organisations %			
Yes	6 (50)	10 (90.9)	0.094
No	6 (50)	1 (9.1)	
Hobbies			
Includes physical movement	6 (50)	10 (90.9)	0.090
Non-active	10 (83.3)	8 (72.7)	0.912
Most significant exercise%			
Walking	8 (66.7)	8 (72.7)	0.890
Gardening	7 (58.3)	7 (63.6)	0.867
Gym - organised exercise	1 (8.3)	8 (72.7)	**0.006**

a= P values obtained using two-tailed independent samples t-test.
b= P values obtained using chi^2 with Yates correction.

4.1.3 Medical characteristics

4.1.3.1 Breast Cancer Treatment

The type of breast cancer treatment reported was similar between groups. The stage of invasive carcinoma was high. The most common type of surgery was mastectomy (15/23; 65.2%), occurred primarily on the right side (15/23; 65.2%), and involved post-surgical fluid removal (18/23; 78.3%). The most common area of radiotherapy was the chest wall (14/23; 60.9%), followed by axilla and chest wall (5/23; 21.7%). More women in the intervention group experienced severe effects from chemotherapy (n=7; 58.3%) compared to control (n=4; 36.4%), and also effects from radiotherapy (n=8; 66.7%) compared to control (n=3; 27.3%). The three women who had reconstruction were all in the intervention group. Baseline descriptive data for breast cancer treatment appears in Table 4.2.

Table 4.2 *Breast Cancer Treatment.*

Characteristic	Intervention (n=12) n (%)	Control (n=11) n (%)	P value[b]
Breast cancer Surgery			
Lumpectomy	5 (41.7)	3 (27.3)	
Mastectomy	5 (41.7)	7 (63.6)	0.882
Lump followed by mastectomy	2 (16.7)	1 (9.1)	
Side of surgery			
Left	4 (33.3)	3 (27.3)	
Right	7 (58.3)	6 (54.5)	0.978
Both	1 (8.3)	2 (18.2)	
Type of breast cancer			
Ductal carcinoma in situ	0	1 (9.1)	
Invasive carcinoma	12 (100)	10(90.9)	0.976
N.B. Three women were diagnosed with secondary breast cancer during the trial.			
Stage of breast cancer			
0	0	1 (9.1)	
1	3 (25)	4 (36.4)	0.976
2	6 (50)	5 (45.5)	
3	3 (25)	1 (9.1)	
Treatment and effects			
Chemotherapy	8 (66.7)	6 (54.5)	0.867
Effects chemotherapy	7 (58.3)	4 (36.4)	0.525
Radiotherapy	9 (75)	7 (63.6)	0.890
Effects radiotherapy	8 (66.7)	3 (27.3)	0.198
Tamoxifen/Aromatase	7 (58.3)	6 (54.5)	0.811
Herceptin®	3 (25)	1 (9.1)	0.649
Most common area of radiotherapy			
Chest	7 (58.3)	7 (63.6)	
Axilla	2 (16.7)	2 (18.2)	0.909
Axilla and chest	3 (25)	2 (18.2)	
Other post-surgery effects			
Post-surgery infections	3 (25)	3 (27.3)	0.725
Post-surgery cording	3 (25)	3 (27.3)	0.725
Post-surgery fluid removal	9 (75)	9 (81.8)	0.913
Reconstruction	3 (25)	0	0.246

b=P values obtained using chi^2 with Yates correction

4.1.3.2 Lymphoedema

Groups were similar. Most women reported axillary node dissection (22/23; 95.6%), and only one had sentinel node biopsy. The average number of nodes removed was 13±8.6 (range 2-30). Participants had experienced lymphoedema for an average of 5.2±6 years (range one month-23 years). The mean time for receiving a diagnosis of BCRL post-surgery was 1.6±1.9 years (range one month to 8 years). Wearing of compression sleeves was relatively high (17/23; 73.9%). Baseline descriptive data for lymphoedema is given in Table 4.3.

Table 4.3 *Medical Conditions-Lymphoedema.*

Characteristic	Intervention (n=12)	Control (n=11)	P value[a]
Number nodes removed			
Mean ± SD	14.3±2.6	11.2±2.7	0.429
Range	5-30	2-25	
Number of positive nodes			
Mean ± SD	1.5±0.5	3.7±2.3	0.321
Range	0-5	0-24	
How long lymphoedema (years)			
Mean ± SD	4.9±1.6	5.5±1.9	0.900
Range	6 months-20 years	1 month-23 years	
How long post-surgery (years)			
Mean ± SD	1.2±0.4	1.9±0.7	0.822
Range	1 month-5 years	1 month-8 years	
	n (%)	**n (%)**	**P value[b]**
Lymphoedema			
Clinically diagnosed	12(100)	11(100)	1.000
L-dex>10	5 (41.7)	3 (27.3)	0.770
Lymphoedema dominant/non-dominant			
Dominant	7 (58.3)	7 (63.6)	0.867
Non-dominant	5 (41.7)	4 (36.4)	
Lymphoedema side			
Left	4 (33.3)	4 (36.4)	0.774
Right	8 (66.7)	7 (63.6)	
Type of lymph dissection			
Sentinel node	0	1 (9.1)	
Axillary clearance	9 (75)	8 (72.7)	0.980
Both	3 (25)	2 (18.2)	
Lymphoedema trunk/breast	3 (25)	3 (27.3)	0.725
Compression sleeve			
Wear	9 (75)	8 (72.7)	0.725

a=P values obtained using two-tailed independent samples t-test.
b=P values obtained using chi^2 with Yates correction.

All women in the trial except one had two or more risk factors. The number of women with each risk factor in the whole group and L-dex>10 sub-group is illustrated in Table 4.4.

Table 4.4 *Incidence of Common Risk Factors for Development of Lymphoedema at Baseline.*

Risk factor	Total (n=23) n (%)	Ldex>10 (n=8) n (%)	Missing values(n=23) n
More than 5 nodes removed	18 (78.3)	8 (100)	2 don't know
Post-operative infection	6 (26.1)	3 (37.5)	
Radiation to axilla	9 (39.1)	5 (62.5)	
BMI >30	4 (17.4)	1 (12.5)	
BMI>25	15 (65.2)	4 (50)	
Surgery mastectomy M	12 (52.2)	3 (37.5)	
lumpectomy L followed by M	3 (13)	1 (12.5)	
total	15 (65.2)	4 (50)	
Axillary dissection	22 (95.7)	8 (100)	
2 or more risk factors	22 (95.7)	8 (100)	
4 or more risk factors	12 (52.2)	7 (87.5)	

(Based on Thomas-Maclean et al., 2008, p 69, with addition of axillary dissection and surgery type).

4.1.3.3 Other medical conditions

Allergies (10/23; 43.5%) and arthritis (13/23; 56.5%) were commonly reported in both groups. The norm for allergies in Australia is 19.6% (Australian Bureau of Statistics, 2006). The norm for arthritis in Australian women in a similar age bracket is 20% (Access Economics Pty Ltd, 2007). Fifteen of the 23 women (65.2%) reported having a lumbar problem, compared to a lower number reporting thoracic and cervical problems. The characteristics of other medical conditions are provided in Table 4.5.

Table 4.5 *Other Medical and Musculoskeletal Conditions.*

Condition	Intervention (n=12) n (%)	Control (n=11) n (%)
Allergies	6 (50)	4 (36.4)
Arthritis	6 (50)	7 (63.6)
Thyroid problems	4 (33.3)	1 (9.1)
Lumbar problems	9 (75)	6 (54.5)
Thoracic problems	2 (16.7)	2 (18.2)
Cervical problems	4 (33.3)	4 (36.4)
Shoulder problems	1 (8.3)	2 (18.2)
Depression	2 (16.7)	2 (18.2)

4.1.4 Lymphoedema: treatment and effects

There were no major differences between the intervention and control groups. The most common sensations were pain (15/23; 65.2%) and heaviness (10/23; 43.5%). The actions that caused problems were repetitious movement (14/23; 60.9%), excessive activity (14/23; 60.9%). heavy lifting (12/23; 52.2%) and exerting downward pressure (10/23; 43.5%). While lymphoedema affected their life (11/23; 47.8%), most felt they "just had to get on with life" (17/23; 73.9%) and were not embarrassed about their condition (16/23; 69.6%). Baseline descriptive data for treatment and effects of lymphoedema is given in Table 4.6.

Table 4.6 *Lymphoedema: Treatment and Effects.*

Characteristic	Intervention (n=12) n (%)	Control (n=11) n (%)	P value[b]
Original treatment			
Complex lymphoedema therapy (CLT)	10 (83.3)	9 (81.8)	1.000
Current treatment			
Regular CLT	5 (41.7)	2 (18.2)	0.442
MLD	4 (33.3)	6 (54.4)	0.546
Self-massage	2 (16.7)	3 (27.3)	0.913
Compression sleeve	9 (75)	8 (72.7)	0.725
Sensations when done too much			
First sensation			
Heavy	5 (41.7)	5 (45.5)	0.811
Tightness	3 (25)	3 (27.3)	0.725
Aches	3 (25)	3 (27.3)	0.725
Tingling	2 (16.7)	0	0.499
Other	0	2 (18.2)	0.421
Fullness	0	1 (9.1)	0.964
None	1 (8.3)	1 (9.1)	0.499
What alleviates this feeling			
Rest	5 (41.7)	7 (63.6)	0.525
Self-massage	5 (41.7)	1 (9.1)	0.193
Elevation	1 (8.3)	1 (9.1)	0.499
Nothing	1 (8.3)	0	0.964
Feel pain from lymphoedema			
Yes	9 (75)	6 (54.5)	0.554
Cause			
No comment	3 (25)	4 (36.4)	0.890
Overuse	2 (16.7)	1 (9.1)	0.933
Driving	1 (8.3)	0	0.964
Carrying bag	1 (8.3)	1 (9.1)	0.499
Gardening	1 (8.3)	1 (9.1)	0.499
Tight clothing	1 (8.3)	0	0.164
Other	3 (25)	3 (27.3)	0.725
What alleviates pain			
Rest	6 (50)	2 (18.2)	0.245
Sleeve	2 (16.7)	0	0.499
Nothing	0	2 (18.2)	0.421
Elevation	1 (8.3)	1 (9.1)	0.499
Self-massage	1 (8.3)	0	0.964
Cooling it	0	1 (9.1)	0.964

Characteristic	Intervention (n=12) n (%)	Control (n=11) n (%)	P value[b]
Embarrassment			
Yes	3 (25)	4 (36.4)	0.964
No	9 (75)	7 (63.6)	
Cause of embarrassment			
Other people's comments	3 (25)	4 (36.4)	0.890
Does lymphoedema stop you doing anything? (if so, what?)			
Yes	6 (50)	6 (54.5)	0.841
Heavy lifting	5 (41.7)	7 (63.6)	0.525
Heavy labour	3 (25)	5 (45.5)	0.555
Sport	4 (33.3)	3 (27.3)	0.890
Holding tightly	4 (33.3)	3 (27.3)	0.890
Other	4 (33.3)	5 (45.5)	0.867
Difficulty from lymphoedema			
Downward pressure	5 (41.7)	5 (45.5)	0.811
Weight from above	4 (33.3)	5 (45.5)	0.867
What makes your lymphoedema worse			
Repetitious movement	9 (75)	5 (45.5)	0.306
Heat	5 (41.7)	8 (72.7)	0.386
Too much activity	7 (58.3)	7 (63.6)	0.867
Writing, scissors, knitting	6 (50)	2 (18.2)	0.245
Carrying	2 (16.7)	6 (54.5)	0.143
Being overweight	0	0	1.000
Does lymphoedema affect your life			
Yes	6 (50)	5 (45.5)	0.841
How			
Just have to get on with life	10 (83.3)	7 (63.6)	0.549
Careful in what I do	9 (75)	9 (81.8)	0.913
Clothing	4 (33.3)	5 (45.5)	0.867
Affects everything	4 (33.3)	3 (27.3)	0.890
May get worse	3 (25)	3 (27.3)	0.725
Stress			
Do you have much stress?	4 (33.3)	4 (36.4)	0.775
Does lymphoedema increase stress?	1 (8.3)	2 (18.2)	0.933

b=P value obtained using chi^2 with Yates correction.

4.1.5 Intervention compliance

Both class attendance and DVD compliance were high in Hobart and Launceston, as illustrated in Table 4.7. Percentages were based on the number of classes attended out of a possible eight and the number of DVD sessions completed at home out of a possible 48. Missed classes in Hobart were due to travelling for work.

Table 4.7 *Compliance by Intervention Group: Class Attendance and DVD Compliance.*

Location	Class attendance %	DVD compliance %
Hobart n=9	94%	82%
Launceston n=6	100%	92%
Total n=15	97%	86%

4.2 Primary outcomes

4.2.1 Lymphoedema levels: L-dex, arm volume and hand volume

Baseline scores did not vary significantly for *L-dex, arm volume* or *hand volume*. There were no significant between group results from b-8. The intervention group mean reduced significantly in *arm volume* from b-8 (p=0.029), illustrated in *Figure 4.2*. The scores for *L-dex* and *hand volume* did not increase in the intervention group from b-8. Trends for *L-dex* and *hand volume* are presented in *Figure 4.3* and *Figure 4.4*, respectively. Full results for lymphoedema b-8 are presented in Table 4.8.

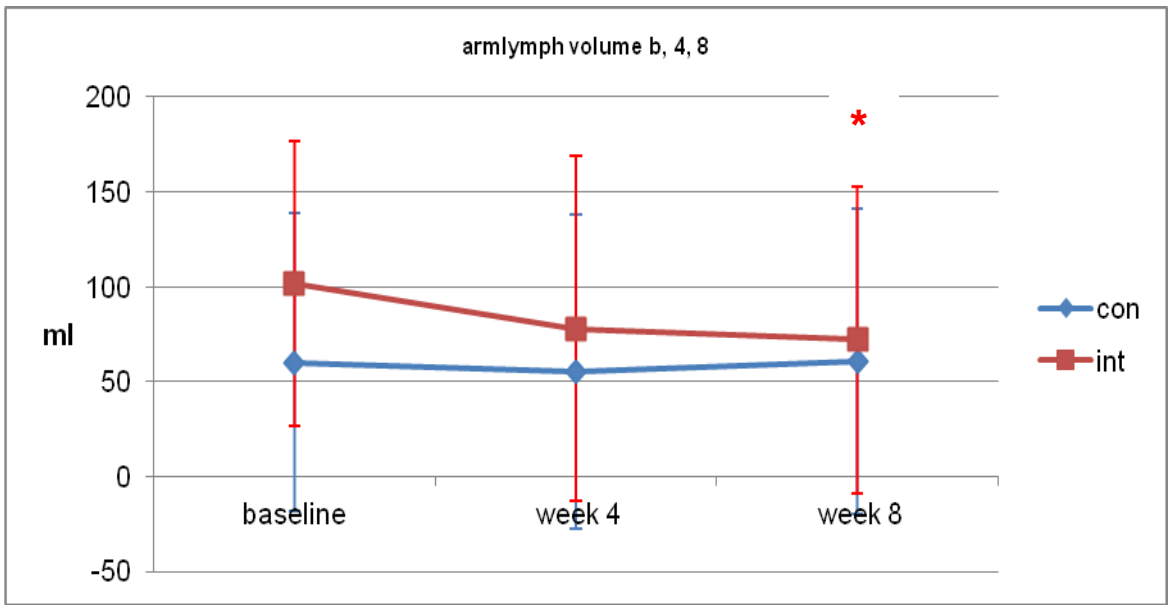

Figure 4.2 Comparison con & int group means ± SDs, b-8, lymphoedema: *arm volume*.

*=significant result int group from baseline to week 8.

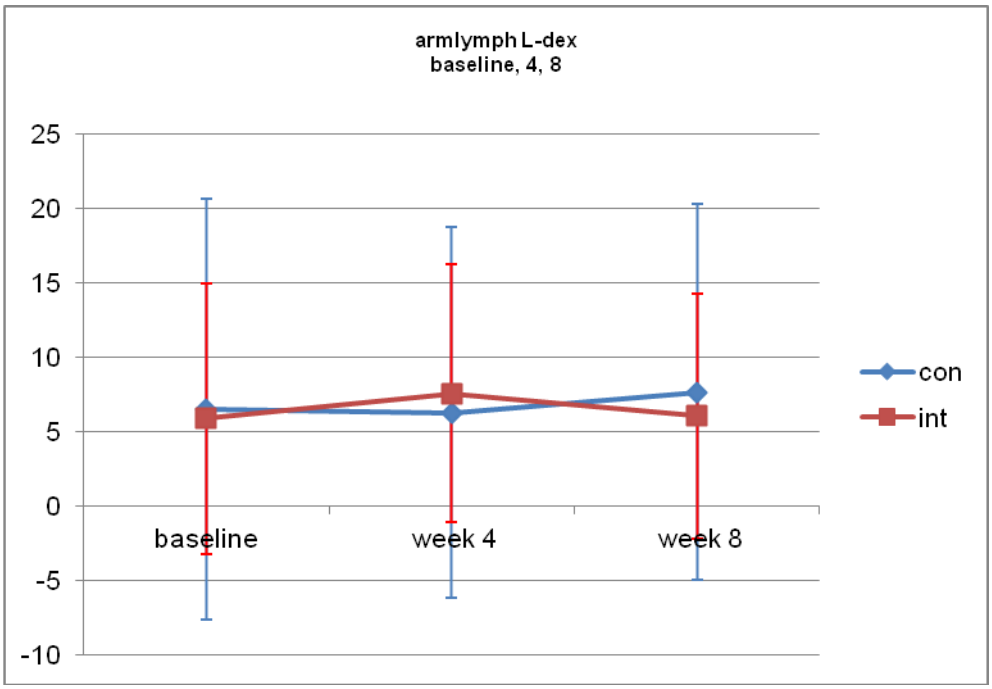

Figure 4.3 Comparison con & int group means ± SDs, b-8, lymphoedema: *L-dex*.

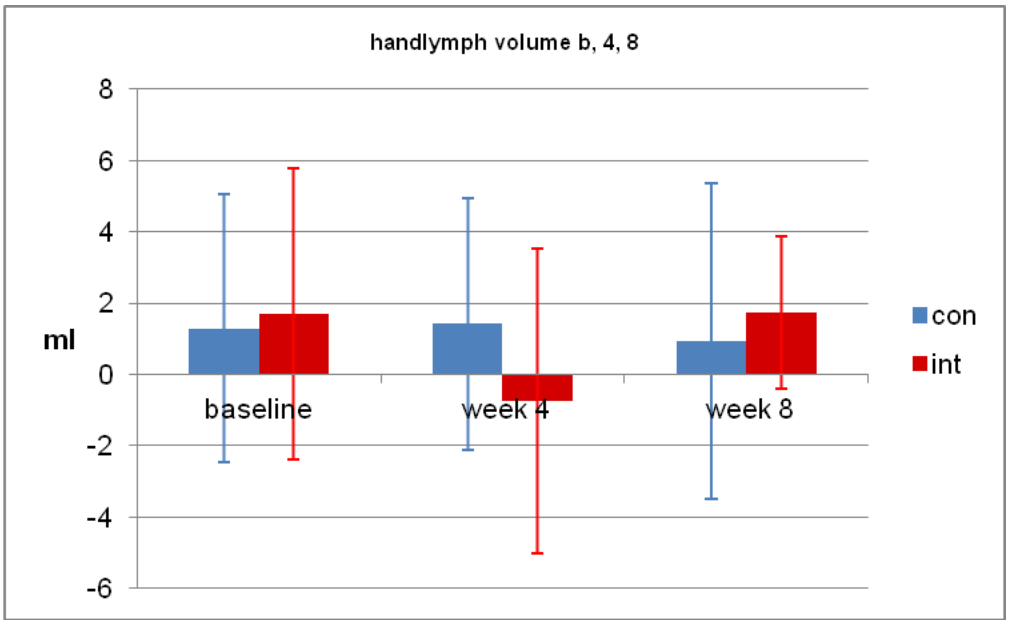

Figure 4.4 Comparison con & int group means ± SDs, b-8, lymphoedema: *hand volume.*

Table 4.8 *Results Lymphoedema b-8*

LYMPHOEDEMA Within group changes b-8 **Between group changes b-8**

Variable/Gp	Week 0 m±SD	Week 4 m±SD	P (0-4)	Week 8 m±SD	P (0-8)	∆int-∆con 0-4 Md; (95% CI)	P	∆int-∆con 0-8 Md; (95% CI)	P
L-dex									
Con n=11	6.49±14.14	6.28±12.45	0.856	7.66±12.64	0.310	1.88; (-1.26 to 5.01)	0.241	-1.03; (-4.17 to 2.10)	0.519
Int n=12	5.89±9.07	7.56±8.66	0.132	6.03±8.24	0.898				
Arm volume									
Con n=10	59.89±78.53	55.27±82.50	0.754	60.75±80.69	0.954	-18.89; (-57.94 to 20.16)	0.343	-30.28; (-69.33 to 8.78)	0.129
Int n=12	101.45±75.08	77.94±90.63	0.080	72.03±80.77	**0.029***				
Hand volume									
Con n=10	1.29±3.75	1.41±3.52	0.864†	0.93±4.44	0.979†	-2.55; (-5.65 to 0.54)	0.317†	0.42; (-2.67 to 3.51)	0.932†
Int n=12	1.69±4.09	-0.74±4.27	0.140†	1.75±2.14	0.926†				

***p<0.05** †=non-parametric analysis ∆=change

From 8b-12, there was a significant between group result in the whole group for *arm volume* of lymphoedema (p=0.032) and in the L-dex>10 sub-group (p=0.032), due to a decrease in the control group and a significant increase in the intervention group (p=0.026). These significant between group and within group results are presented graphically in *Figure 4.5*. There were no significant results for *L-dex* and *hand volume* from 8b-12. Full results for lymphoedema 8b-12 appear in Table 4.9.

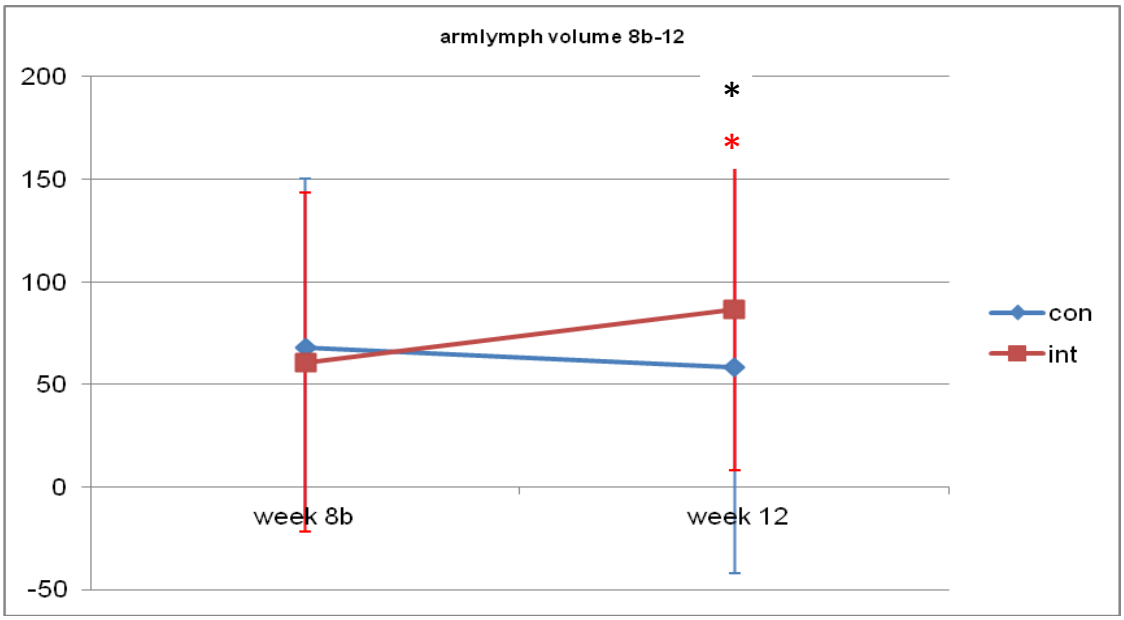

Figure 4.5 Comparison con & int group means ± SDs, 8b-12, lymphoedema: *arm volume*.

*=significant between group result from 8b to week 12.
*=significant result int group from 8b to week12.

Table 4.9 *Results Lymphoedema 8b-12.*

LYMPHOEDEMA Within group changes 8b-12 Between group changes 8b-12

Variable/Gp	Week 8b m±SD	Week 12 m±SD	P (8b-12)	Δint-Δcon 8b-12 Md; (95% CI)	P
L-dex					
Con n=10	8.68±12.83	7.83±13.59	0.498	2.57; (-1.04 to 6.18)	0.163
Int n=9	4.96±6.40	6.67±7.08	0.201		
Arm volume					
Con n=9	67.65±82.39	58.17±100.42	0.413	35.20; (3.09 to 67.32)	**0.032***
Int n=9	60.82±82.84	86.53±78.29	**0.026***		
Hand volume					
Con n=9	0.68±4.63	0.90±4.25	0.840	-0.26; (-3.32 to 2.80)	0.870
Int n=9	1.91±2.46	1.88±2.96	0.976		

***p<0.05** Δ=change

4.2.2 Tissue density

Baseline scores did not vary significantly between groups for *tissue density*, measured by tonometer, for the *affected* and *non-affected forearm*, *upper arm*, *chest* or *upper back*. From b-8, there was a significant between group result in favour of the intervention group in tissue density for the *affected upper arm* in the whole group (p=0.050) and in the L-dex>10 sub-group (p=0.040). This was due to an increase in the control group and a decrease in the intervention group, as illustrated in *Figure 4.6*. From b-8, the intervention group mean reduced significantly for the *affected chest* (p=0.044). There were no other significant results. Full results for tonometry b-8 are presented in Table 4.10.

Apart from the *forearm* scores, all tonometry scores in both groups at baseline were higher for the *affected* than for the *non–affected* arm or side, which would be expected with the formation of fibrous tissue from lymphoedema. By week 8, however, the intervention group had a **lower** score for the *affected chest* than for the *non-affected chest*.

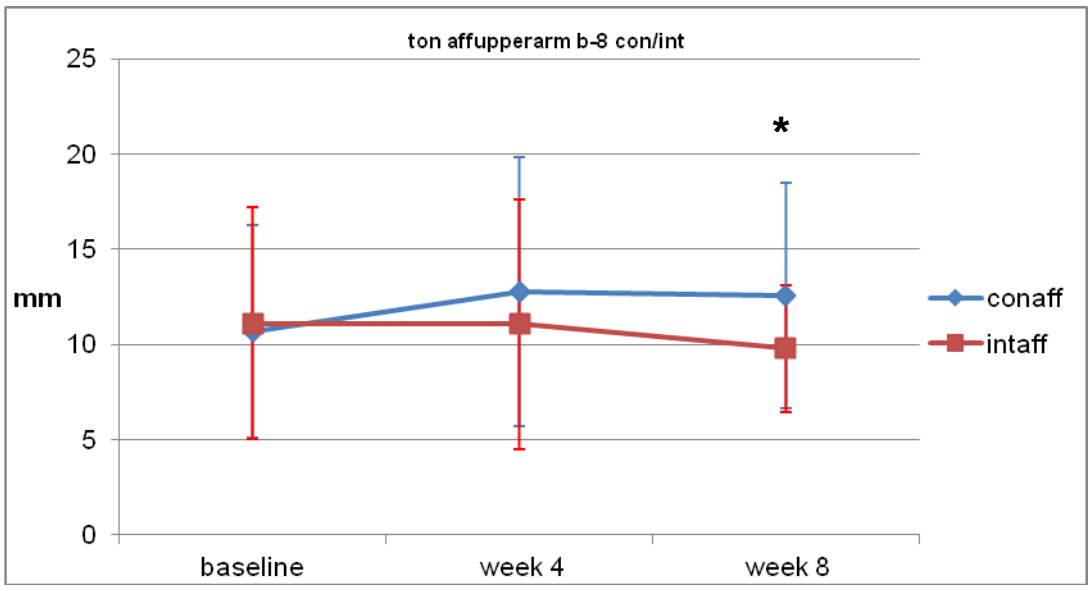

Figure 4.6 Comparison con & int group means ± SDs, b-8, tonometry: *affected upper arm*.

*=significant between group result.

Table 4.10 *Results Tonometry b-8.*

TONOMETRY	Within group changes b-8					Between group changes b-8			
Variable/Gp	**Week 0 m±SD**	**Week 4 m±SD**	**P (0-4)**	**Week 8 m±SD**	**P (0-8)**	**Δint-Δcon 0-4 Md; (95% CI)**	**P**	**Δint-Δcon 0-8 Md; (95% CI)**	**P**
Forearm affected									
Con n=11	13.96±3.82	15.85±5.25	0.089	14.06±4.80	0.927	-2.09; (-5.12 to 0.93)	0.174	-1.86; (-4.88 to1.16)	0.227
Int n=12	15.78±4.79	15.58±4.72	0.849	14.02±3.59	0.099				
Forearm non-affected									
Con n=11	15.61±4.17	16.02±4.41	0.726	15.81±5.20	0.864	-0.18; (-3.36 to 3.00)	0.913	-1.40; (-4.59 to1.78)	0.387
Int n=12	15.92±5.51	16.15±6.32	0.836	14.72±5.42	0.284				
Upper arm affected									
Con n=11	10.66±5.57	12.76±7.05	0.075	12.54±5.91	0.112	-2.16; (-5.36 to1.05)	0.188	-3.20; (-6.41 to 0)	**0.050***
Int n=12	11.10±6.09	11.05±6.56	0.964	9.77±3.33	0.241				
Upper arm non-affected									
Con n=10	10.14±4.42	11.22±5.61	0.328	12.05±6.26	0.084	-1.00; (-3.94 to1.95)	0.507	-2.88; (-5.82 to 0.06)	0.055
Int n=12	9.88±4.09	9.97±5.12	0.929	8.91±3.62	0.340				
Chest affected									
Con n=11	6.78±2.39	7.35±2.90	0.496	5.53±3.41	0.134	-0.99; (-3.26 to1.29)	0.395	-0.36; (-2.63 to1.91)	0.758
Int n=12	6.34±2.01	5.92±1.56	0.605	4.73±1.75	**0.044***				
Chest non-affected									
Con n=11	5.59±1.84	6.63±2.80	0.442†	4.76±2.65	0.106†	-0.84; (-3.35 to 1.66)	-0.508†	-0.34; (-2.85 to 2.17)	0.878†
Int n=12	6.06±1.87	6.27±2.19	0.933†	4.90±1.97	0.281†				
Upper back affected									
Con n=11	16.17±2.39	16.98±4.31	0.581	16.76±4.32	0.688	1.04; (-2.93 to 5.00)	0.608	0.19; (-3.77 to 4.16)	0.924
Int n=12	16.06±4.18	17.91±4.60	0.187	16.84±4.82	0.577				
Upper back non-affected									
Con n=11	14.32±3.87	15.51±4.34	0.345	15.23±5.54	0.469	0.41; (-3.02 to 3.84)	0.815	-1.42; (-4.85 to 2.02)	0.419
Int n=12	15.55±4.21	17.15±5.48	0.185	15.05±4.86	0.679				

***p<0.05** †=non-parametric analysis Δ=change

From 8b-12, there were no significant changes in tissue density between the groups. Tissue density improved significantly for the *non-affected forearm*, *affected* and *non-affected upper arm,* and *affected upper back* in both groups, shown in the table below. Full results for 8b-12, with p values, are presented in Table 4.11.

At week 12, the intervention group maintained the lower score for the *affected chest* in comparison to the *non-affected chest*. This also occurred for the *upper back*. The control group had lower scores for both the *affected forearm* and *upper back*.

Table 4.11 *Results Tonometry 8b-12*

TONOMETRY	**Within group changes 8b-12**			**Between group changes 8b-12**	
Variable/Gp	**Week 8b m±SD**	**Week 12 m±SD**	**P (8b-12)**	**∆int-∆con 8b-12 Md; (95% CI)**	**P**
Forearm affected					
Con n=10	13.65±4.85	12.45±4.35	0.15	-0.43; (-2.77 to1.92)	0.72
Int n=9	13.87±3.68	12.26±2.41	0.06		
Forearm non-affected					
Con n=10	15.37±5.27	12.66±4.00	**0.02***	0.10; (-3.09 to 3.30)	0.95
Int n=9	14.68±6.23	12.07±4.28	**0.03***		
Upper arm affected					
Con n=9	12.08±6.02	8.92±5.19	**0.001***	0.95; (-1.40 to 3.30)	0.43
Int n=9	9.63±3.53	7.42±4.39	**0.01***		
Upper arm non-affected					
Con n=10	11.46±6.34	7.97±5.18	**0.001***	0.53; (-1.98 to 3.03)	0.68
Int n=9	8.17±3.54	5.21±3.10	**0.001***		
Chest affected					
Con n=10	5.22±3.43	5.76±1.50	0.51	-0.60; (-2.94 to 1.73)	0.61
Int n=9	4.23±1.14	4.17±1.09	0.95		
Chest non-affected					
Con n=10	4.70±2.79	6.18±5.00	0.30	-1.22; (-5.33 to 2.90)	0.56
Int n=9	4.98±2.23	5.25±1.60	0.86		
Upper back affected					
Con n=10	16.48±4.45	13.21±5.06	**0.001***	1.10; (-1.51 to 3.70)	0.41
Int n=9	15.81±4.28	13.63±2.93	**0.02***		
Upper back non-affected					
Con n=10	15.04±5.79	14.43±4.32	0.61	-0.48; (-3.90 to 2.95)	0.78
Int n=9	14.66±5.33	13.58±3.83	0.39		

***p<0.05** ∆=change

4.2.3 Level of sensations, pain, fatigue and degree to which they limited daily activity

Baseline scores did not vary significantly for the level of *sensations*, *pain* and *fatigue* and their *limiting effects*. There was a significant between group result at week 4 in the whole group for *pain limiting activity* (p=0.035) and in the L-dex>10 sub-group (p=0.043), due to an increase in the control group in the degree to which *pain limited its activity* (p=0.032) and a non-significant decrease in the intervention group. There was also a significant **decrease** in *pain* level in the control group at week 4 (p=0.050). At week 8 and from 8b-12, there were no significant between or within group results. Group means for sensations, pain and fatigue decreased from b-8 and increased from 8b-12 for the intervention group. Sensations and fatigue scored higher than pain throughout the trial in both groups.

Women recorded varied *sensations* at each measurement. Both groups experienced *sensations* they described as heavy, warm, hot, tingly, tight, numb and aching, with a noticeable reduction in heaviness and numbness in the intervention group from baseline measurement. The frequency of reported *sensations* is presented in Table 4.12.

Full results for VAS from b-8 are presented in Table 4.13. Full results for VAS from 8b-12 are presented in Table 4.14.

Table 4.12 *Self-Report of Sensations at Each Measurement in Control and Intervention.*

Sensation	Group	n	Baseline	Wk 4	Wk 8	Wk 12
Heavy	Con	11	6	6	3	6
	Int	12	8	5	2	2
Warm	Con	11	0	1	4	1
	Int	12	2	6	4	3
Hot	Con	11	1	0	1	0
	Int	12	0	0	1	0
Tingly	Con	11	1	3	0	1
	Int	12	3	2	2	2
Tight	Con	11	3	2	1	1
	Int	12	3	2	2	2
Numb	Con	11	0	2	2	1
	Int	12	6	2	2	2
Aching	Con	11	6	2	2	3
	Int	12	5	3	4	3

Table 4.13 *Results VAS b-8*

VAS	Within group changes b-8					Between group changes b-8			
Variable/Gp	**Week 0 m±SD**	**Week 4 m±SD**	**P (0-4)**	**Week 8 m±SD**	**P (0-8)**	**∆int-∆con 0-4 Md; (95% CI)**	**P**	**∆int-∆con 0-8 Md; (95% CI)**	**P**
Sensations									
Con n=11	1.97±1.89	2.66±1.74	0.134†	2.01±2.15	0.645†	-0.14; (-1.92 to 1.64)	0.718†	-0.55; (02.33 to 1.23)	0.345†
Int n=12	2.39±2.12	2.94±2.52	0.589†	1.88±1.83	0.406†				
Pain									
Con n=11	1.69±2.31	1.11±1.53	**0.050***	1.44±2.24	0.391	0.66; (-0.15 to 1.46)	0.110	0.06; (-0.74 to 0.87)	0.878
Int n=12	0.99±1.53	1.07±1.88	0.792	0.80±1.48	0.500				
Fatigue									
Con n=11	1.71±2.21	1.53±1.42	0.309†	2.06±2.52	0.205†	0.18; (-1.28 to 1.64)	0.421†	-1.05; (-2.50 to 0.41)	0.117†
Int n=12	2.58±2.60	2.58±2.76	0.968†	1.88±2.23	0.327†				
Sensations limit activity									
Con n=11	1.35±2.81	1.49±2.75	0.315†	0.93±1.90	0.556†	-0.25; (-1.73 to 1.23)	0.664†	-0.18; (-1.66 to 1.30)	0.793†
Int n=12	1.43±1.76	1.33±1.48	0.583†	0.83±0.74	0.773†				
Pain limit activity									
Con n=11	0.57±1.10	1.37±2.73	**0.032*†**	1.31±2.39	0.054†	-1.30; (-2.37 to -0.23)	**0.035*†**	-0.99; (-2.06 to 0.09)	0.362†
Int n=12	0.81±1.44	0.31±0.37	0.186†	0.56±0.58	0.508†				
Fatigue limit activity									
Con n=11	0.69±1.51	0.74±1.05	0.337†	1.34±2.57	0.173†	-0.60; (-1.95 to 0.76)	0.196†	-1.09; (-2.44 to 0.27)	0.315†
Int n=12	1.38±1.85	0.83±1.13	0.355†	0.93±0.95	0.918†				

***p<0.05** †=non-parametric analysis ∆=change

Table 4.14 *Results VAS 8b-12*

VAS		Within group changes 8b-12		Between group changes 8b-12	
Variable/Gp	**Week 8b m±SD**	**Week 12 m±SD**	**P (8b-12)**	**∆int-∆con 8b-12 Md; (95% CI)**	**P**
Sensations					
Con n=10	2.20±2.17	2.20±2.12	1	0.30; (-1.21 to 1.81)	0.698
Int n=9	1.96±1.59	2.26±2.29	0.592		
Pain					
Con n=10	1.57±2.31	1.16±1.48	0.307	0.81; (-0.33 to 1.95)	0.165
Int n=9	1.00±1.67	1.40±1.84	0.345		
Fatigue					
Con n=10	2.26±2.56	1.57±1.54	0.264†	0.42; (-1.45 to 2.30)	0.551†
Int n=9	2.37±2.50	2.10±1.77	0.964†		
Sensations limit activity					
Con n=10	1.01±1.98	0.81±1.70	0.504	0.37; (-0.49 to 1.22)	0.399
Int n=9	1.03±0.73	1.20±1.54	0.597		
Pain limit activity					
Con n=10	1.42±2.49	0.89±1.59	0.320	0.72; (-0.80 to 2.24)	0.353
Int n=9	0.61±0.58	0.80±0.93	0.737		
Fatigue limit activity					
Con n=10	1.46±2.67	1.07±1.74	0.425	0.61; (-0.78 to 2.00)	0.389
Int n=9	1.03±0.95	1.26±1.24	0.666		

***p<0.05** †=non-parametric analysis ∆=change

4.2.4 Quality of Life

Baseline scores did not vary significantly for QOL *total score* or *sub-scales*. There were no between group results from b-8 for total QOL however a trend was apparent. From b-8 and 8b-12, the control group mean stayed within a narrow range for *total QOL* scores, while the intervention group mean slowly increased (improved), though not significantly. The comparison between groups, including SDs, for total QOL, b-8 and 8b-12, is represented graphically in *Figure 4.7*.

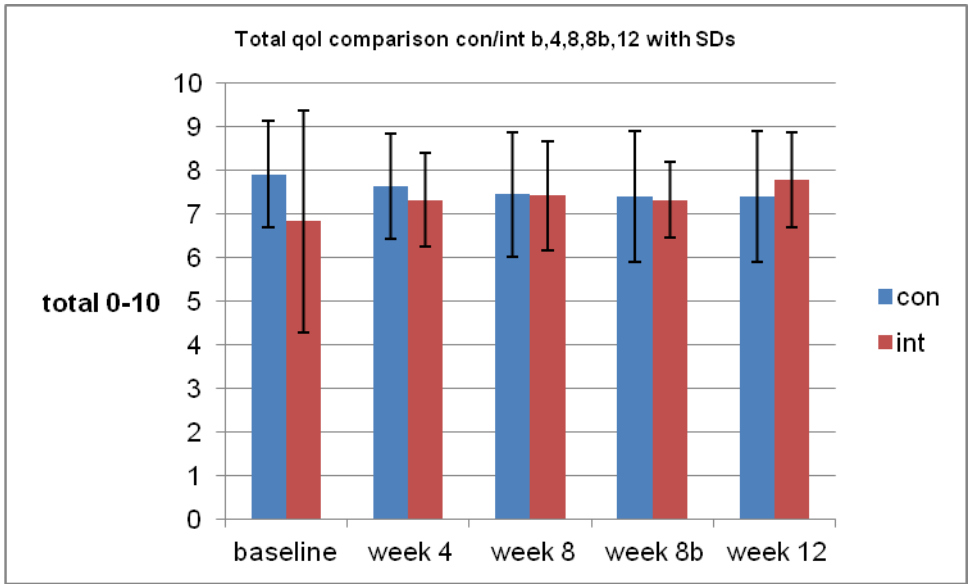

Figure 4.7 Comparison con & int group means ± SDs, b-8 and 8b-12, *total QOL.*

From b-8, there was a significant between group result in the sub-scale of *symptoms* in the whole group (p=0.038) and in the L-dex>10 sub-group (p=0.035), due to an increase in the control group and a decrease in the intervention group. There were no other significant results between or within groups from b-8. The full results for *total QOL* and the QOL sub-scales from b-8 are presented in Table 4.15.

Table 4.15 *Results Total QOL and QOL Sub-Scales b-8.*

QOL	Within group changes b-8					Between group changes b-8			
Variable/Gp	**Week 0 m±SD**	**Week 4 m±SD**	**P (0-4)**	**Week 8 m±SD**	**P (0-8)**	**∆int-∆con 0-4 Md; (95% CI)**	**P**	**∆int-∆con 0-8 Md; (95% CI)**	**P**
Total QOL									
Con n=11	7.91±1.22	7.64±1.21	0.282†	7.45±1.44	0.364†	0.77; (-0.45 to 2.00)	0.718†	1.04; (-0.19 to 2.26)	0.437†
Int n=12	6.83±2.55	7.33±1.07	0.895†	7.42±1.24	0.848†				
Function sub-scale									
Con n=11	1.36±0.40	1.26±0.26	0.593†	1.30±0.36	0.605†	0.08; (-1.13 to 0.29)	0.823†	-0.13; (-0.34 to 0.09)	0.364†
Int n=12	1.48±0.48	1.46±0.51	0.910†	1.30±0.31	0.136†				
Appearance sub-scale									
Con n=11	1.56±0.81	1.56±0.70	1	1.56±0.86	1	0.05; (-0.22 to 0.32)	0.715	-0.07; (-0.34 to 0.20)	0.627
Int n=11	1.50±0.34	1.55±0.37	0.598	1.43±0.33	0.482				
Symptoms sub-scale									
Con n=11	1.69±0.37	1.70±0.50	0.913†	1.82±0.54	0.310†	-0.16; (-0.46 to 0.14)	0.552†	-0.44; (-0.74 to -0.13)	**0.038*†**
Int n=12	2.11±0.61	1.96±0.45	0.393†	1.81±0.40	0.057†				
Emotions sub-scale									
Con n=11	1.71±0.56	1.63±0.55	0.638	1.61±0.49	0.538	-0.15; (-0.59 to 0.29)	0.516	-0.18; (-0.62 to 0.26)	0.430
Int n=12	1.86±0.74	1.64±0.60	0.152	1.58±0.77	0.074				

***p<0.05** †=non-parametric analysis ∆=change

From 8b-12, there were no significant between group results. However, both groups recorded a significant result. The control group mean for *symptoms* decreased (improved) (p=0.027). The intervention group mean for *function* increased (worsened) (p=0.026). The full results for total QOL and the QOL sub-scales from 8b-12 are presented in Table 4.16.

The change that occurred for *symptoms,* including significant results, from b-8 and 8b-12, for both groups is presented in *Figure 4.8*.

Table 4.16 *Results Total QOL and QOL Sub-Scales 8b-12.*

QOL	Within group changes 8b-12			Between group changes 8b-12	
Variable/Gp	**Week 8b m±SD**	**Week 12 m±SD**	**P (8b-12)**	**Δint-Δcon 8b-12 Md; (95% CI)**	**P**
Total QOL					
Con n=10	7.40±1.51	7.40±1.51	1.000	0.44; (-0.38 to 1.27)	0.290
Int n=9	7.33±0.87	7.78±1.09	0.145		
Function sub-scale					
Con n=10	1.31±0.38	1.35±0.33	0.603	0.13; (-0.07 to 0.33)	0.210
Int n=9	1.34±0.33	1.51±0.14	**0.026***		
Appearance sub-scale					
Con n=10	1.60±0.89	1.60±0.69	1	0.10; (-0.25 to 0.45)	0.578
Int n=9	1.42±0.37	1.52±0.37	0.443		
Symptoms sub-scale					
Con n=10	1.90±0.49	1.73±0.47	**0.027***	0.17; (-0.05 to 0.39)	0.124
Int n=9	1.91±0.38	1.91±0.40	0.978		
Emotions sub-scale					
Con n=10	1.62±0.52	1.60±0.56	0.875	0.04; (-0.24 to 0.31)	0.801
Int n=9	1.44±0.45	1.46±0.43	0.843		

***p<0.05** Δ=change

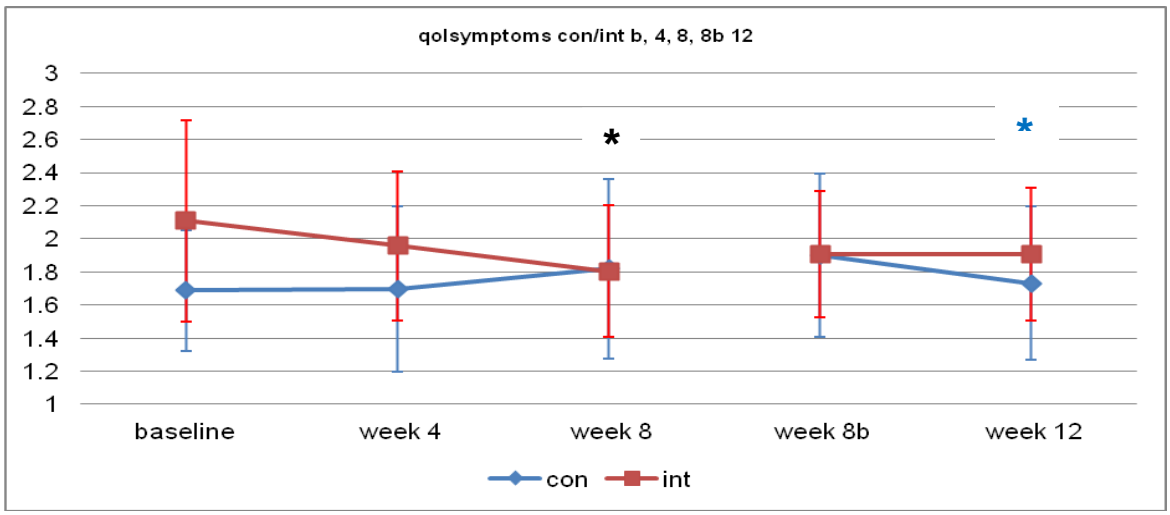

Figure 4.8 Comparison con & int group means ± SDs, b-8 and 8b-12, *symptoms* sub-scale.

*=significant between group result.
*=significant result con group.

4.3 Secondary outcomes

4.3.1 Range of motion of the shoulder (ROM)

Baseline scores did not vary significantly for shoulder ROM. There were two significant between group results from b-8 in favour of the control group. In the control group there was an increase in *flexion* for the non-affected arm (p=0.001), which resulted in a significant between group difference in the whole group (p= 0.011) and in the L-dex >10 sub-group (p=0.008), at week 8. At week 8 there was also an increase for *abduction* for the non-affected arm in the control group and an increase in the intervention group, and this created another significant between group difference in the whole group (p=0.049)and in the L-dex >10 sub-group(p=0.039). The result for abduction of the non-affected arm between groups from b-8 and 8b-12, showing the significant result at week 8, 8b is illustrated in *Figure 4.9*.

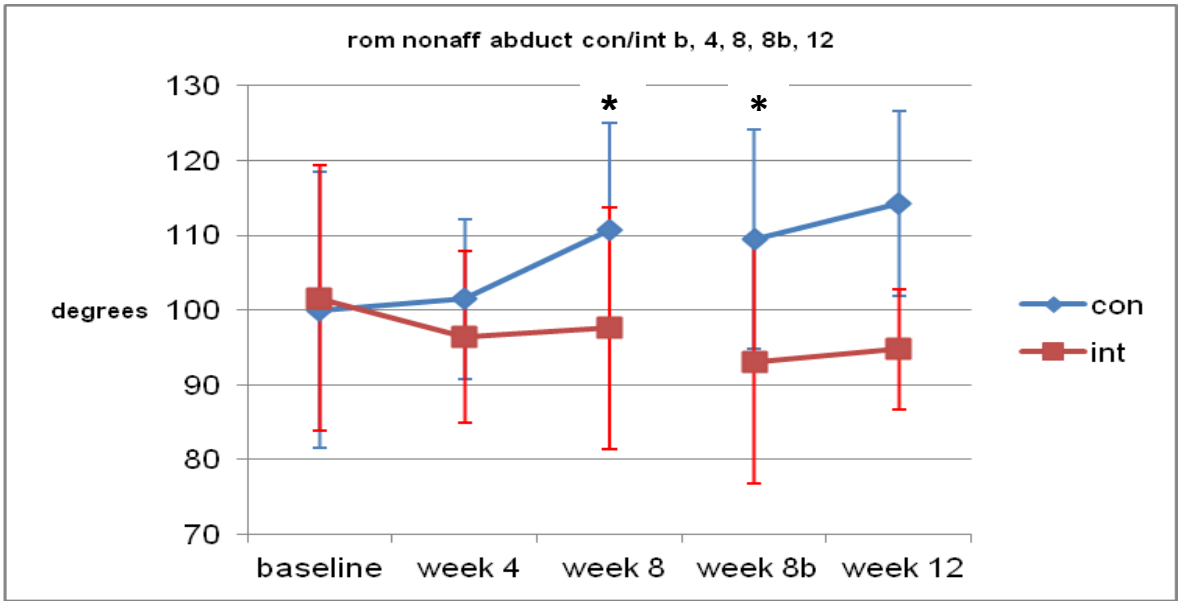

Figure 4.9 Comparison con & int group means ± SDs, b-8 & 8b-12, *abduction* non-aff arm.

*=significant between group result.

The change created by this between group result in *abduction* revealed a change in the way each group used both arms at week 8. At week 8, the intervention group had a similar score in ROM *abduction* for both arms, compared to the difference between arms at baseline. From 8b-12, the difference between arms occurred once more. The control group had a parallel increase in both arms from b-8 and 8b-12. The pattern for each group was typical for all ROM actions except *extension*. The different results for *abduction* for the control group and intervention group, b-8 and 8b-12, are presented in *Figure 4.10*.

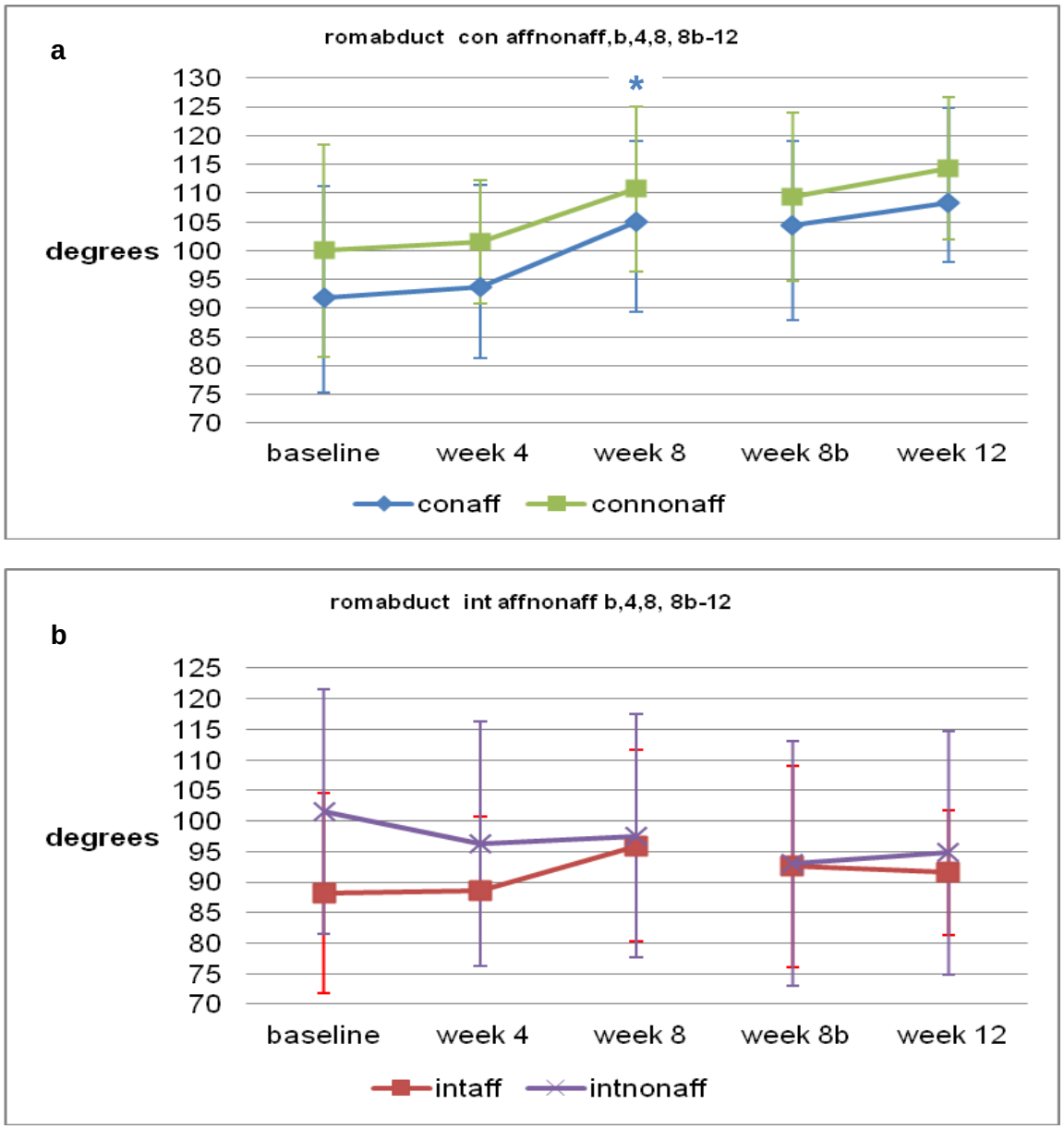

Figure 4.10 Comparison aff & non-aff arms in a. con group and b. int group, b-8; 8b-12, *abduction*.

*=significant result.

From b-8, both groups had a number of significant within group results in various actions. The control group had significant improvements in *flexion* for the affected arm at week 4 (p=0.014) and week 8 (p=0.001), and for the non-affected arm at week 4 (p=0.050) and week 8 (p=0.001); in *internal rotation* for the non-affected arm at week 8 (p=0.031); in *extension* for the affected arm at week 8 (p=0.030) and the non-affected arm at week 4 (p=0.030) and week 8 (p=0.005); in *abduction* for the affected arm at week 8 (p=0.008); and in *external rotation* for the affected arm at week 8 (p=0.041).

The intervention group had significant improvements in *flexion* for the affected arm at week 8 (p=0.005); in *internal rotation* for the affected arm at week 8 (p=0.050); and in *extension* for the affected arm (p=0.003) and the non-affected arm (p=0.021) at week 8.

Full results for shoulder ROM, b-8, are presented in Table 4.17.

Table 4.17 *Results Shoulder ROM b-8.*

ROM	Within group changes b-8					Between group changes b-8			
Variable/Gp	**Week 0 m±SD**	**Week 4 m±SD**	**P (0-4)**	**Week 8 m±SD**	**P (0-8)**	**∆int-∆con 0-4 Md; (95% CI)**	**P**	**∆int-∆con 0-8 Md; (95% CI)**	**P**
Abduction affected									
Con n=11	91.82±19.46	93.64±17.72	0.715	105.00±14.01	**0.008***	-1.49;(-15.00 to12.03)	0.830	-5.43;(-18.95 to 8.08)	0.431
Int n=12	88.17±16.45	88.50±12.24	0.944	95.92±15.70	0.104				
Abduction non-affected									
Con n=10	100.00±18.45	101.50±10.67	0.785	110.70±14.36	0.052	-6.75;(-21.35 to 7.85)	0.365	-14.70;(-29.30 to -0.10)	**0.049***
Int n=12	101.58±17.75	96.33±11.47	0.296	97.58±16.19	0.426				
Flexion affected									
Con n=11	101.82±17.31	112.82±14.70	**0.014***	121.18±16.89	**0.001***	-5.50;(-17.60 to 6.60)	0.373	-7.45;(-19.45 to 4.65)	0.228
Int n=12	103.75±12.47	109.25±13.56	0.198	115.67±12.49	**0.005***				
Flexion non-affected									
Con n=10	106.10±13.80	116.90±14.42	**0.050***	126.60±13.37	**0.001***	-10.72;(-25.36 to 3.93)	0.152	-19.00;(-33.65 to -4.36)	**0.011***
Int n=12	110.08±10.23	110.17±12.52	0.987	111.58±15.66	0.766				
Internal rotation affected									
Con n=11	47.18±20.24	48.09±17.70	0.989†	52.82±18.76	0.526†	7.01;(-7.05 to 21.07)	0.443†	6.86;(7.20 to 20.92)	0.448†
Int n=12	45.83±14.53	53.75±7.81	0.198†	58.33±11.51	**0.050*†**				
Internal rotation non-affected									
Con n=10	47.40±10.43	55.90±14.72	0.124	59.30±13.12	**0.031***	-8.67;(-23.34 to 6.00)	0.247	-6.15;(-20.8 to 8.52)	0.411
Int n=12	53.00±17.49	52.83±9.81	0.974	58.75±14.72	0.255				
Extension affected									
Con n=11	38.36±9.29	42.45±8.93	0.217	48.27±8.92	**0.030***	-1.17;(-10.17 to 7.83)	0.798	-0.41;(-9.41 to 8.59)	0.929
Int n=12	35.42±11.45	38.33±11.15	0.358	44.92±11.65	**0.003***				
Extension non-affected									
Con n=10	39.50±9.25	45.10±6.15	**0.030*†**	48.30±4.45	**0.005*†**	-1.85;(-11.00 to 7.30)	0.772†	3.03;(-6.12 to 12.18)	0.768†
Int n=12	37.42±12.10	41.17±9.95	0.374†	49.25±11.69	**0.021*†**				
External rotation affected									
Con n=11	65.54±11.89	69.09±5.75	0.556†	71.00±6.29	**0.041*†**	-4.62;(14.77 to 5.53)	0.420†	-2.20;(-12.34 to 7.95)	0.360†
Int n=12	63.33±20.28	62.17±12.42	0.554†	66.50±11.12	0.945†				
External rotation non-affected									
Con n=10	70.50±14.30	70.50±11.97	1	71.60±14.20	0.702	-0.83;(-8.46 to 6.80)	0.831	-2.35;(-9.98 to 5.28)	0.546
Int n=12	69.08±12.32	68.25±9.99	0.751	67.83±12.10	0.634				

***p<0.05** †=non-parametric analysis ∆=change

From 8b-12, there was a significant between group result in favour of the control group in *internal rotation* for the affected arm in the whole group (p=0.001)and in the L-dex>10 sub-group (p=0.001). This was due to the increase in the control group and the significant reduction in the intervention group (p=0.005). Full results for shoulder ROM, 8b-12, are presented in Table 4.18.

Table 4.18 *Results ROM 8b-12.*

ROM	**Within group changes 8b-12**			**Between group changes 8b-12**	
Variable/Gp	**Week 8b m±SD**	**Week 12 m±SD**	**P (8b-12)**	**∆int-∆con 8b-12 Md; (95% CI)**	**P**
Abduction affected					
Con n=10	104.40±14.62	108.30±16.49	0.344	-4.90; (-16.64 to 6.84)	0.413
Int n=9	92.56±16.48	91.56±10.25	0.818		
Abduction non-affected					
Con n=9	109.44±14.64	114.22±12.37	0.305	-3.00; (-15.92 to 9.92)	0.649
Int n=9	93.00±16.17	94.78±8.03	0.703		
Flexion affected					
Con n=10	119.80±17.14	122.50±16.96	0.530	-1.37; (13.61 to 10.87)	0.827
Int n=9	112.22±12.62	113.56±13.87	0.769		
Flexion non-affected					
Con n=9	125.33±13.53	126.44±16.68	0.847	4.89; (-11.12 to 20.89)	0.549
Int n=9	106.89±15.26	112.89±15.50	0.299		
Internal rotation affected					
Con n=10	52.70±19.77	57.00±19.43	0.056	-10.97; (-17.37 to -4.56)	**0.001***
Int n=9	58.78±11.44	52.11±13.08	**0.005***		
Internal rotation non-affected					
Con n=9	59.22±13.91	55.11±15.07	0.316	1.67; (-9.71 to 13.04)	0.774
Int n=9	59.00±15.98	56.56±11.78	0.551		
Extension affected					
Con n=10	48.20±9.40	51.60±7.81	0.147	-5.96; (-12.64 to 0.73)	0.081
Int n=9	42.33±12.21	39.78±10.65	0.302		
Extension non-affected					
Con n=9	47.89±4.51	51.78±7.26	0.120	-6.33; (-13.27 to 0.60)	0.073
Int n=9	48.89±13.37	46.44±11.22	0.328		
External rotation affected					
Con n=10	70.30±6.17	72.50±6.65	0.282	-4.20; (-10.02 to 1.62)	0.157
Int n=9	64.56±12.20	62.56±9.83	0.353		
External rotation non-affected					
Con n=9	70.89±14.87	72.44±13.69	0.353	0.89; (-3.76 to 5.53)	0.708
Int n=9	63.67±10.28	66.11±11.25	0.145		

***p<0.05** ∆=change

4.3.2 Strength

4.3.2.1 Grip strength

There were no significant differences between groups in *grip strength* at baseline or weeks 4 and 8.

From 8b-12, there was a significant between group result in *grip strength* for the affected arm in favour of the intervention group in the whole group (p=0.010) and in the L-dex>10 sub-group (p=0), due to a significant reduction in the control group (p=0.002). The results for grip strength are presenteddwith the results for shoulder strength in Table 4.19 (b-8) and Table 4.20 (8b-12).

4.3.2.2 Strength of the shoulder

There were no significant between group differences for shoulder strength at baseline or weeks 4, 8, 8b and 12.

From b-8, the control group had three significant within group results at week 4: an increase for the non-affected arm in *flexion* (p=0.047) and in *horizontal adduction* (p=0.026) and a **decrease** in extension for the affected arm (p=0.008).

From b-8, the intervention group had significant improvements in *abduction* for the affected and non-affected arms at weeks 4 and week 8. The affected arm increased at week 4 (p=0.004) and at week 8 (p=0.042), while the non-affected arm increased at week 4 (p=0.004) and at week 8 (p=0.045). The results for shoulder strength and grip strength, b-8, are presented in Table 4.19.

Table 4.19 *Results Shoulder and Grip Strength b-8.*

STRENGTH	**Within group changes b-8**					**Between group changes b-8**			
Variable/Gp	**Week 0 m±SD**	**Week 4 m±SD**	**P (0-4)**	**Week 8 m±SD**	**P (0-8)**	**∆int-∆con 0-4 Md; (95% CI)**	**P**	**∆int-∆con 0-8 Md; (95% CI)**	**P**
Grip affected									
Con n=11	24.59±5.95	23.36±5.04	0.272	25.45±3.94	0.439	2.19; (-0.84 to 5.22)	0.157	-.091; (-3.94 to 2.13)	0.558
Int n=12	25.08±8.94	26.04±8.64	0.370	25.04±7.35	0.969				
Grip non-affected									
Con n=10	25.50±3.50	25.00±3.50	0.555	25.25±3.89	0.768	1.17; (-1.08 to 3.42)	0.309	1.58; (-0.67 to 3.83)	0.168
Int n=12	23.75±7.08	24.42±7.31	0.389	25.08±6.88	0.085				
Abduction affected									
Con n=11	66.69±27.75	72.18±21.50	0.261	71.11±22.16	0.365	7.88; (-5.37 to 21.12)	0.244	5.08; (-8.16 to 18.33)	0.452
Int n=12	56.83±23.26	70.29±26.28	**0.004***	66.33±22.82	**0.042***				
Abduction non-affected									
Con n=10	71.82±28.95	80.06±21.00	0.174	75.24±21.77	0.573	8.45; (-7.97 to 24.87)	0.313	8.16; (-8.26 to 24.58)	0.330
Int n=11	59.18±23.76	75.87±26.91	**0.004***	70.76±26.07	**0.045***				
Flexion affected									
Con n=11	73.13±24.33	74.95±21.73	0.725	78.51±29.09	0.298	4.38; (-9.65 to 18.41)	0.540	-2.83; (-16.86 to 11.20)	0.692
Int n=12	70.17±24.20	76.37±25.79	0.210	72.72±24.34	0.606				
Flexion non-affected									
Con n=10	69.04±24.44	80.82±15.54	**0.047***	79.78±28.66	0.071	-2.38; (-18.47 to 13.71)	0.772	-5.54; (-21.63 to 10.55)	0.500
Int n=11	68.53±30.45	77.93±26.58	0.097	73.73±25.17	0.359				
Extension affected									
Con n=11	93.44±18.33	75.98±16.30	**0.008***	82.51±31.07	0.098	9.53; (-8.41 to 27.47)	0.298	-0.59; (-18.53 to 17.35)	0.949
Int n=12	81.85±30.26	73.93±28.34	0.210	70.33±29.12	0.069				
Extension non-affected									
Con n=10	88.72±20.82	80.74±15.56	0.263	87.84±29.56	0.902	6.94; (-12.37 to 26.26)	0.481	-8.94; (-28.25 to 10.37)	0.364
Int n=11	78.58±26.33	77.55±26.65	0.879	68.76±20.62	0.149				
Horizontal adduction affected									
Con n=11	58.00±19.86	64.20±15.43	0.122	60.80±15.41	0.485	-0.97; (-11.85 to 9.92)	0.862	-1.88; (-12.77 to 9.00)	0.734
Int n=12	55.73±18.56	60.97±16.26	0.173	56.65±13.60	0.811				
Horizontal adduction non-affected									
Con n=10	59.60±21.42	69.40±12.27	**0.026***	63.80±13.44	0.356	-2.34; (14.66 to 9.98)	0.710	-7.40; (-19.72 to 4.92)	0.239
Int n=11	58.20±19.24	66.00±18.90	0.072	55.00±14.82	0.461				

***p<0.05** †=non-parametric analysis ∆=change

There were no significant within group results from 8b-12. The intervention group achieved similar scores between arms in *flexion* and *horizontal adduction* at week 8, which it sustained to week 12, with the addition of *abduction*. This only occurred in the control group in *flexion* at week 8. Full results for shoulder and grip strength are presented in Table 4.20.

Table 4.20 *Results Shoulder and Grip Strength 8b-12*

STRENGTH	**Within group changes 8b-12**			**Between group changes 8b-12**	
Variable/Gp	**Week 8b m±SD**	**Week 12 m±SD**	**P (8b-12)**	**∆int-∆con 8b-12 Md; (CI 95%)**	**P**
Grip affected					
Con n=10	24.80±3.47	21.55±3.72	**0.002*†**	3.58; (1.50 to 5.67)	**0.010*†**
Int n=9	24.39±7.70	24.72±8.52	0.525†		
Grip non-affected					
Con n=9	24.39±2.95	24.06±2.19	0.672	0.83; (-1.35 to 3.02)	0.455
Int n=9	23.22±6.36	23.72±7.04	0.526		
Abduction affected					
Con n=10	71.18±23.36	64.42±21.17	0.074	2.89; (-7.88 to 13.67)	0.599
Int n=9	64.49±23.54	60.62±31.69	0.332		
Abduction non-affected					
Con n=9	75.29±23.09	70.09±19.62	0.220	-1.20; (13.28 to 10.88)	0.846
Int n=9	68.75±26.45	61.02±22.61	0.153		
Flexion affected					
Con n=10	79.10±30.60	76.04±30.64	0.506	-0.56; (-13.67 to 12.54)	0.933
Int n=9	71.53±26.62	67.91±27.82	0.455		
Flexion non-affected					
Con n=9	81.07±30.09	83.91±30.38	0.525	-8.53; (-21.31 to 4.25)	0.191
Int n=9	74.98±26.73	69.84±31.86	0.230		
Extension affected					
Con n=10	83.06±32.69	79.52±26.76	0.504	-3.82; (-18.89 to 11.26)	0.620
Int n=9	64.51±27.04	57.16±25.52	0.187		
Extension non-affected					
Con n=9	86.60±31.08	87.64±32.16	0.833	-3.90; (-18.03 to 10.23)	0.588
Int n=9	67.33±20.67	65.69±28.97	0.585		
Horizontal adduction affected					
Con n=10	60.06±16.04	58.52±20.06	0.644	-4.82; (-14.32 to 4.69)	0.321
Int n=9	54.02±13.21	47.67±8.23	0.071		
Horizontal adduction non-affected					
Con n=9	63.56±14.23	66.47±18.32	0.376	-8.54; (-17.90 to 0.84)	0.074
Int n=9	53.90±13.04	47.91±9.12	0.105		

***p<0.05** †=non-parametric analysis ∆=change

4.3.2.3 Strength of pectoralis major, pectoralis minor and serratus anterior.

Baseline scores did not vary significantly for strength of *pectoralis major*, *pectoralis minor* and *serratus anterior*. There were no significant between group results from b-8 for these muscles.

From b-8, significant within group results occurred for *serratus anterior* at weeks 4 and 8 in both groups, except for the control group's affected side at week 4. Significant results for serratus anterior with p values are presented in the full results for *pectoralis major*, *pectoralis minor* and *serratus anterior,* b-8, in Table 4.21.

Apart from the control group's affected *serratus anterior*, the baseline scores were lower for the affected side than the non-affected side for all other measures, as would be expected for women with BCRL.

Table 4.21 *Results Pectoralis Major, Pectoralis Minor, Serratus Anterior b-8.*

SEPARATE MUSCLES	Within group changes b-8					Between group changes b-8			
Variable/Gp	**Week 0 m±SD**	**Week 4 m±SD**	**P (0-4)**	**Week 8 m±SD**	**P (0-8)**	**∆int-∆con 0-4 Md; (95% CI)**	**P**	**∆int-∆con 0-8 Md; (95% CI)**	**P**
Pectoralis major affected									
Con n=11	53.99±18.91	54.55±21.02	0.0897	53.40±14.36	0.891	1.65; (-10.01 to 13.30)	0.782	-2.16; (-13.82 to 9.50)	0.717
Int n=12	54.82±21.97	57.02±21.07	0.593	52.07±17.05	0.504				
Pectoralis major non-affected									
Con n=10	55.00±18.26	59.40±16.37	0.230	57.20±14.67	0.549	-1.84; (-11.77 to 8.10)	0.717	-4.60; (-14.52 to 5.33)	0.364
Int n=11	58.40±21.63	60.96±21.21	0.464	56.00±19.04	0.493				
Pectoralis minor affected									
Con n=11	25.80±6.89	28.20±5.28	0.190	28.80±4.77	0.101	-0.02; (-4.98 to 4.95)	0.995	-0.98; (-5.95 to 3.98)	0.698
Int n=12	26.95±5.79	29.33±4.99	0.174	28.97±4.48	0.250				
Pectoralis minor non-affected									
Con n=11	27.40±8.93	27.80±4.64	0.879	29.20±6.82	0.495	1.60; (-5.71 to 8.91)	0.668	-0.80; (-8.11 to 6.51)	0.830
Int n=11	27.00±8.81	29.00±6.51	0.448	28.00±7.24	0.705				
Serratus anterior affected									
Con n=11	37.77±7.02	45.76±16.06	0.104	46.00±15.16	0.059	6.77; (-4.28 to 17.83)	0.230	1.09; (-9.93 to 12.10)	0.847
Int n=12	35.86±13.88	48.88±12.55	**0.001***	44.18±12.18	**0.008***				
Serratus anterior non-affected									
Con n=10	33.00±7.89	51.33±15.79	**0.001***	49.94±13.24	**0.001***	2.57; (-4.78 to 9.92)	0.493	-4.28; (-11.46 to 2.90)	0.243
Int n=11	37.18±12.29	52.00±12.10	**0.001***	45.80±10.68	**0.001***				

***p<0.05** ∆=change

From 8b-12, there was a significant between group result for non-affected *pectoralis major* in favour of the control group in the whole group (p=0.002) and in the L-dex>10 sub-group (p=0.001). This was due to an increase in the control group and a significant decrease in the intervention group (p=0.004).

From 8b-12, both groups recorded significant reductions in *pectoralis minor* for both sides. Significant results in pectoralis minor with p values are presented in the full results for pectoralis major, pectoralis minor and serratus anterior, 8b-12, in Table 4.22.

Apart from the between group difference in *pectoralis major* at week 12, the results for these muscles were similar at each measurement between groups, at b-8 and 8b-12, This is illustrated in *Figure 4.11*.

Table 4.22 *Results Pectoralis Major, Pectoralis Minor, Serratus Anterior 8b-12.*

SEPARATE MUSCLES **Within group changes 8b-12** **Between group changes 8b-12**

Variable/Gp	Week 8b m±SD	Week 12 m±SD	P (8b-12)	∆int-∆con 8b-12 Md; (95% CI)	P
Pectoralis major affected					
Con n=10	52.80±14.99	50.38±11.52	0.327	-0.02; (-7.05 to 7.00)	0.995
Int n=9	50.60±16.24	48.16±13.85	0.347		
Pectoralis major non-affected					
Con n=9	54.76±13.22	58.67±15.12	0.133	-11.80; (-19.21 to -4.38)	**0.002***
Int n=9	54.45±18.70	47.18±15.01	**0.004***		
Pectoralis minor affected					
Con n=10	29.48±4.42	22.44±2.27	**0.001***	0.44; (-2.73 to 3.61)	0.786
Int n=9	29.33±3.97	22.73±4.92	**0.001***		
Pectoralis minor non-affected					
Con n=10	29.26±7.19	22.22±5.33	**0.002***	1.46; (-5.11 to 8.03)	0.663
Int n=9	28.60±7.98	22.98±4.68	**0.024***		
Serratus anterior affected					
Con n=10	45.32±15.80	46.20±16.17	0.168†	-3.32; (-13.91 to 7.26)	0.264†
Int n=9	47.44±10.58	44.00±10.08	0.593†		
Serratus anterior non-affected					
Con n=9	50.36±13.98	45.78±15.59	0.190	1.35; (-8.58 to 11.29)	0.789
Int n=9	45.93±9.14	43.27±7.04	0.379		

***p<0.05** †=non-parametric analysis ∆=change

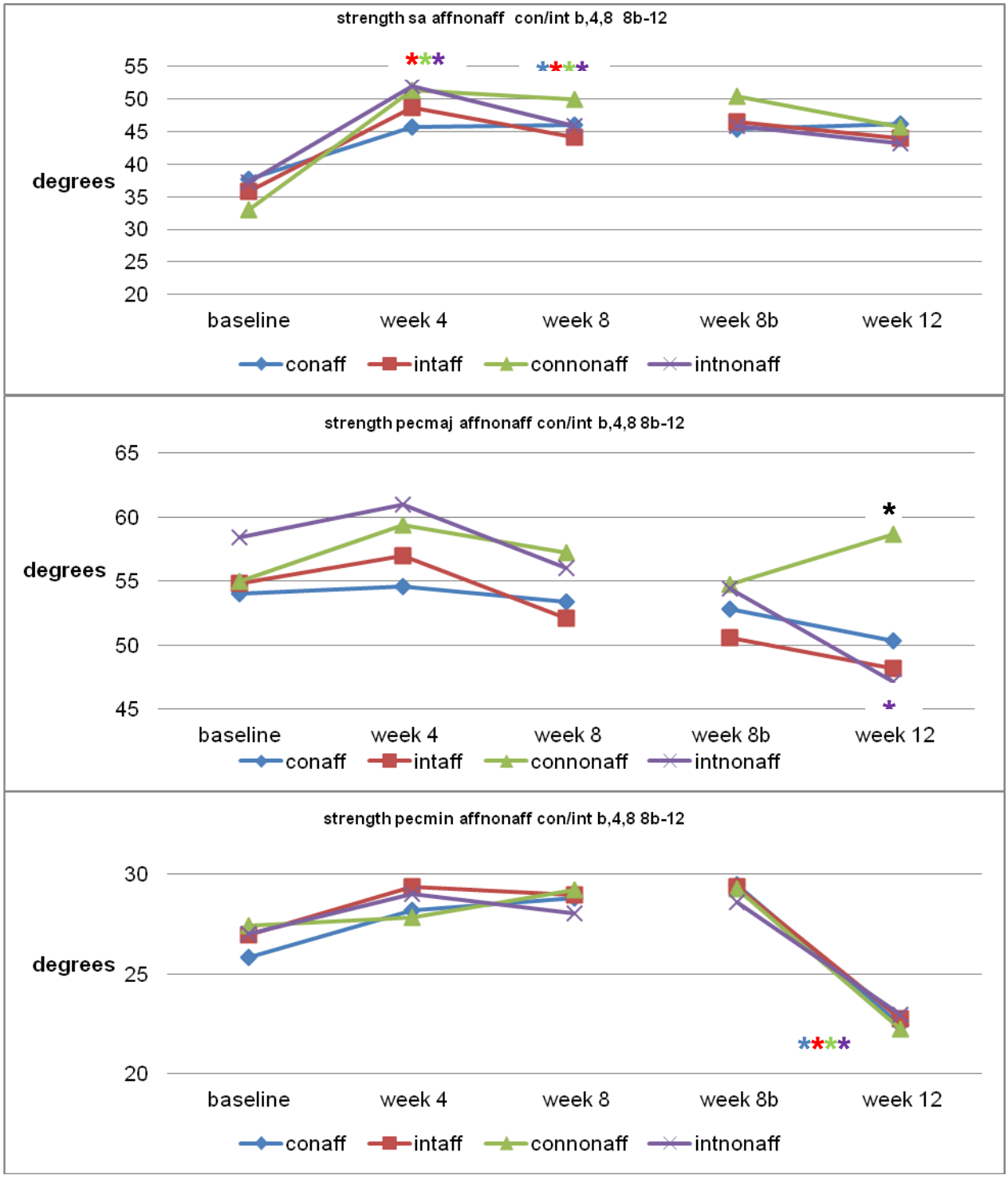

Figure 4.11 Comparison both arms con & int groups, sa, pec major and minor, b-8; 8b-12.

*=significant between group result.
* * * * = significant within group results.

4.3.3 Physical activity

4.3.3.1 Weekly Physical Activity

There were no significant between or within group differences at baseline or at weeks 4, 8, 8b and 12 for *weekly physical activity*. The group mean of the control group was higher than that of the intervention group at all measurements from baseline to week 12, most notably at weeks 8/8b and 12. Both groups' means remained in the *medium* level at each measurement, which corresponded with women's self-report (p 65).

4.3.3.2 Daily Physical Activity

There were no significant between or within group differences at baseline or at weeks 4, 8, 8b and 12 for *daily physical activity*. The group means at every measurement were in the range of 4 to 6, and so are considered *medium*.

Full results for weekly and daily physical activity, b-8 and 8b-12 are presented in Table 4.25.

Table 4.23 *Physical Activity: Weekly and Daily, b-8 and 8b-12.*

PHYSICAL ACTIVITY Within group changes b-8 Between group changes b-8

Variable/Gp	Week 0 m±SD	Week 4 m±SD	P (0-4)	Week 8 m±SD	P (0-8)	∆int-∆con 0-4 Md; (95% CI)	P	∆int-∆con 0-8 Md; (95% CI)	P
Weekly									
Con n=11	3653±73±2358.58	3574.77±2017.26	0.930	3819.96±3574.53	0.854	59.25; (-2396.02 to 2514.51)	0.962	-1126.69; (-3581.95 to 1328.58)	0.368
Int n=12	3228.88±2150.35	3209.17±2954.93	0.982	2268.42±1838.01	0.268				
Daily									
Con n=11	4.14±2.78	4.46±2.76	0.738	4.00±2.69	0.889	0.81; (-1.85 to 3.86)	0.552	0.79; (-1.87 to 3.44)	0.561
Int n=12	4.32±3.00	5.45±1.70	0.226	4.97±2.22	0.488				

PHYSICAL ACTIVITY Within group changes 8b-12 Between group changes 8b-12

Variable/Gp	Week 8b m±SD	Week 12 m±SD	P (8b-12)	∆int-∆con 8b-12 Md; (95% CI)	P
Weekly					
Con n=10	3990.15±3720.61	3237.43±3178.76	0.338†	1383.50; (-135.94 to 2902.94)	0.102†
Int n=9	1911.56±1719.62	2542.33±1480.45	0.145†		
Daily					
Con n=10	4.12±2.81	5.06±3.00	0.384	-0.43; (-3.51 to 2.65)	0.785
Int n=9	4.19±1.95	4.70±3.03	0.654		

†=non-parametric analysis ∆=change

4.3.4 Spinal mobility results – sub-group

Spinal mobility measurements for a self-nominated sub-group were conducted at baseline, weeks 8 and 12. Results are recorded from baseline to week 8 (b-8) and from week 8b to week 12 (8b-12), due to attrition. Static results are reported for *pelvic obliquity* and *angle of kyphosis at rest*, and full range of movement is reported for other measures. There was no analysis of the results for the L-dex>10 sub-groups.

Spinal mobility is reported in *lateral flexion, flexion/extension* and *thoracic rotation*.

4.3.4.1 Demographics

Age and BMI of this sub-group from b-8 and 8b-12 are reported in Table 4.24.

Table 4.24 *Age and BMI (Sub-group Spinal Mobility): Con and Int Group Means ± SDs.*

Characteristic	Intervention	Control
b-8	**n=9**	**n=6**
Age years (m±SD)	55.9±9.1	62.3±5.7
BMI (m±SD)	29.12±5.4	26.39±5.6
8b-12	**n=7**	**n=6**
Age years (m±SD)	55.4±9.8	62.3±5.7
BMI (m±SD)	30.3±5.2	26.39±5.6

4.3.4.2 Lateral flexion of the spine

At baseline, there was a significant difference between groups for *pelvic obliquity* (β1) (p=0.007). The intervention group had a higher score than the control group, showing that it had worse *pelvic obliquity*. There were no other differences between groups for lateral flexion at baseline.

By week 8, there was a significant between group difference for *pelvic obliquity*. Both groups improved; however, the intervention group improved significantly (p=0.001), creating a significant between group result (p=0.023). These results are presented in *Figure 4.12*. There were no further significant between group differences in *lateral flexion* at week 8.

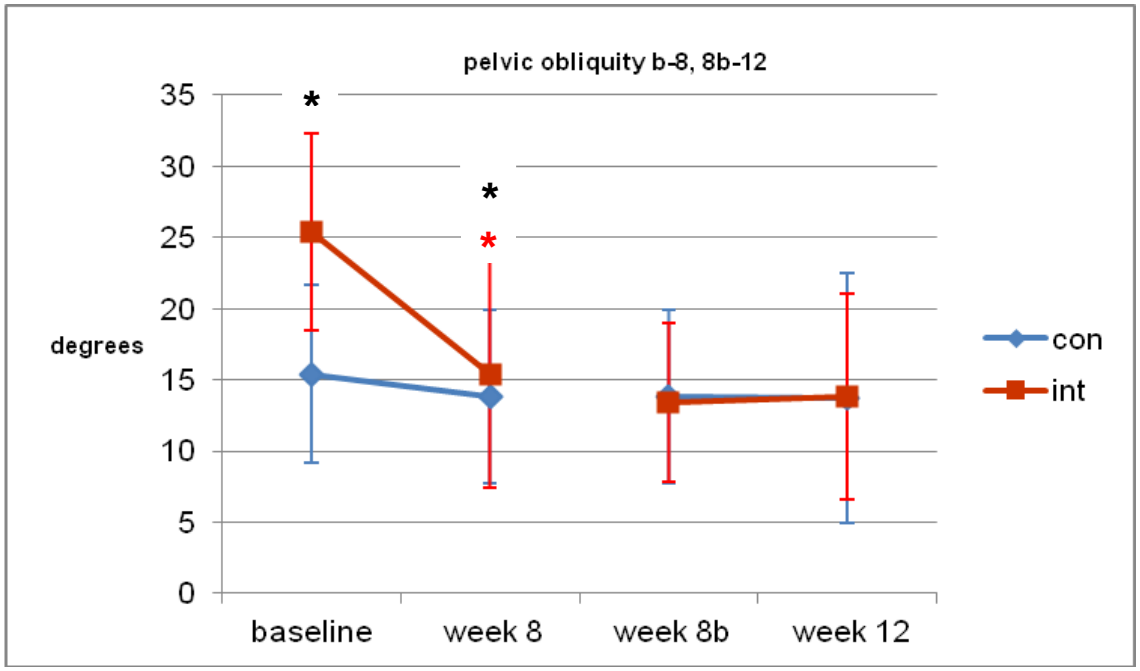

Figure 4.12 Comparison con & int group means ± SDs, b-8; 8b-12, *pelvic obliquity*.

*=significant between group result
*=significant result int group

From b-8, the control group (p=0.024) and the intervention group (p=0.002) both **decreased** in range of *full lateral trunk inclination* (βIti) significantly. Both groups decreased in range of *lumbar lateral flexion* (β2), the control group significantly (p=0.016). There were no further significant results within the groups from b-8, though trends in different areas of movement in the thoracic spine were evident. At week 8, the control group increased its range in the *proximal thoracic spine* (βpc) and the intervention group increased its range in the *distal thoracic spine* (βdc).

Full results in *lateral flexion* of the spine, b-8, are presented in Table 4.25.

At weeks 8b-12 there were no between or within group differences. Full results in *lateral flexion* of the spine, 8b-12, are presented in Table 4.26.

Table 4.25 *Results Lateral Flexion b-8.*

LATERAL FLEXION	**Within group changes b-8**			**Between group changes b-8**			
Variable/Gp	**Week 0 m±SD**	**Week 8 m±SD**	**P (0-8)**	**int-con 0 Md; (95% CI)**	**P**	**∆int-∆con 0-8 Md; (95% CI)**	**P**
Pelvic obliquity β1							
Con n=6	15.40±6.23	13.83±6.09	0.585	9.97; (2.76 to17.17)	**0.007***	-8.39; (-15.64 to -1.13)	**0.023***
Int n=9	25.37±6.90	15.41±7.94	**0.001***				
Lumbar range β2							
Con n=6	24.82±15.37	17.27±9.12	**0.016***	-3.64; (-14.75 to 7.48)	0.521	6.48; (-1.43 to 14.40)	0.109
Int n=9	21.18±10.35	20.11±8.34	0.676				
Thoracic range β3							
Con n=6	48.80±11.71	51.90±3.14	0.286	-3.62; (-15.28 to 8.04)	0.543	0.72; (-6.63 to 8.08)	0.847
Int n=9	45.18±14.55	49.00±10.52	0.107				
Shoulder range β4							
Con n=6	92.08±17.91	86.55±11.96	0.151	0.56; (-22.66 to 23.78)	0.962	3.21; (-6.55 to 12.97)	0.519
Int n=9	92.64±25.78	90.32±26.22	0.461				
Thoracic distal curvature range βdc							
Con n=6	47.83±12.60	48.40±6.16	0.920	-4.11; (-16.59 to 8.37)	0.518	6.50; (-7.70 to 20.70)	0.370
Int n=9	43.72±11.78	50.79±14.59	0.123				
Thoracic proximal curvature range βpc							
Con n=6	29.62±14.55	31.65±9.83	0.663	1.04; (-14.87 to 16.94)	0.898	-5.52; (-17.34 to 6.30)	0.360
Int n=9	30.66±20.07	27.17±13.23	0.360				
Full lateral trunk inclination range βlti							
Con n=6	60.12±13.61	52.70±7.60	**0.024***	4.95; (-9.59 to19.49)	0.505	-0.87; (-9.19 to 7.45)	0.837
Int n=9	65.07±16.45	56.78±14.88	**0.002***				

***p<0.05** †=non-parametric analysis ∆=change

Table 4.26 *Results Lateral Flexion 8b-12*

LATERAL FLEXION	Within group changes 8b-12			Between group changes 8b-12	
Variable/Gp	**Week 8b m±SD**	**Week 12 m±SD**	**P (8b-12)**	**∆int-∆con 8b-12 Md; (95% CI)**	**P**
Pelvic obliquity β1					
Con n=6	13.83±6.09	13.72±8.79	0.972	0.52; (-8.29 to 9.33)	0.908
Int n=7	13.44±5.58	13.84±7.22	0.896		
Lumbar range β2					
Con n=6	17.27±9.12	19.33±6.11	0.512	-5.54; (-13.96 to 2.88)	0.197
Int n=7	20.56±9.12	17.09±4.53	0.234		
Thoracic range β3					
Con n=6	51.90±3.14	55.63±6.16	0.103	-2.91; (-9.02 to 3.21)	0.352
Int n=7	48.86±9.31	49.69±13.22	0.696		
Shoulder range β4					
Con n=6	86.55±11.96	87.77±13.56	0.730	-2.06; (-11.47 to 7.35)	0.668
Int n=7	86.24±26.01	85.40±23.43	0.796		
Thoracic distal curvature range βdc					
Con n=6	48.40±6.16	43.42±8.16	0.102	4.44; (-3.70 to 12.58)	0.285
Int n=7	50.99±16.75	50.44±17.53	0.847		
Thoracic proximal curvature range βpc					
Con n=6	31.65±9.83	34.35±13.48	0.408	-0.54; (-9.26 to 8.18)	0.903
Int n=7	26.20±11.47	28.36±10.77	0.475		
Full lateral trunk inclination βlti					
Con n=6	52.70±7.60	55.22±10.16	0.406	-2.87; (-10.97 to 5.22)	0.486
Int n=7	55.47±15.58	55.11±12.13	0.899		

***p<0.05** ∆=change

4.3.4.3 Flexion/Extension of the spine

At baseline, there were no statistically significant differences between groups in any measure of *flexion/extension* although there were strong trends. The intervention group, compared to the control group, had a higher *angle of thoracic kyphosis at rest* (αkrest) (p=0.053) and reduced range of *thoracic mobility* (α3) (p=0.053).

From b-8, there were no significant between group results for *flexion/extension*. The only significant within group result was for the increase in the control group in range of *full trunk flexion/extension* (αfti) (p=0.016). Although the *thoracic angle of kyphosis at rest* (αkrest) and *thoracic mobility* (α3) improved from b-8 in the intervention group, the results were not significant.

Full results for *flexion/extension* of the spine, b-8, are presented in Table 4.27.

Table 4.27 *Results Flexion/Extension and Spinal Rotation b-8.*

FLEXION/EXTENSION & ROTATION	Within group changes b-8			Between group changes b-8			
Variable/Gp	**Week 0 m±SD**	**Week 8 m±SD**	**P (0-8)**	**int-con 0 Md; (95% CI)**	**P**	**∆int-∆con 0-8 Md; (95% CI)**	**P**
Angle of thoracic kyphosis at rest αkrest							
Con n=6	23.47±8.68	25.80±5.72	0.160	8.13; (-0.10 to 16.37)	0.053	-3.88; (-8.08 to 0.32)	0.070
Int n=9	31.60±10.45	30.06±7.86	0.254				
Thoracic range α3							
Con n=6	58.58±10.03	58.63±10.06	0.995	-15.18; (-30.58 to 0.22)	0.053	5.34; (-15.22 to 25.90)	0.611
Int n=9	43.4±16.90	48.79±17.12	0.417				
Full trunk flexion/extension range αfti							
Con n=6	163.78±20.43	175.02±1.88	**0.016*†**	-27.85; (-57.69 to1.99)	0.098†	7.48; (-31.00 to 45.95)	0.684†
Int n=9	135.93±38.86	154.64±30.64	0.125†				
Thoracic spinal rotation range Tr							
Con n=6	84.23±28.98	87.00±20.01	0.764	-18.01; (-43.77 to 7.75)	0.171	8.28; (-15.05 to 31.60)	0.487
Int n=9	66.22±28.33	77.27±21.07	0.142				

***p<0.05** †=non-parametric analysis ∆=change

From 8b-12, there were no significant between group results. The only significant within group result was for the reduction for the *angle of thoracic kyphosis at rest* (αkrest) in the control group (p=0.039). The changes for *angle of thoracic kyphosis at rest* (αkrest) from b-8 and 8b-12 are illustrated in *Figure 4.13*.

Full results for *flexion/extension* of the spine, 8b-12, are presented in Table 4.28.

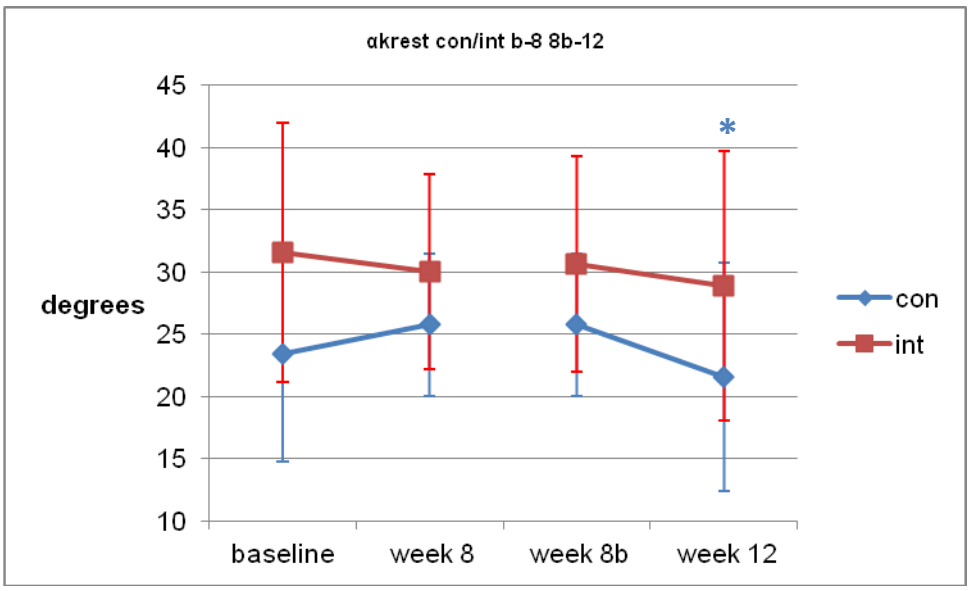

Figure 4.13 Comparison con & int group means ± SDs, b-8; 8b-12, *angle of kyphosis at rest*.

*=significant result con group

Table 4.28 *Results Flexion/Extension and Spinal Rotation 8b-12.*

FLEXION/EXTENSION & ROTATION		Within group changes 8b-12		Between group changes 8b-12	
Variable/Gp	**Week 8b m±SD**	**Week 12 m±SD**	**P (8b-12)**	**Δint-Δcon 8b-12 Md; (95% CI)**	**P**
Angle of thoracic kyphosis at rest αkrest					
Con n=6	25.80±5.72	21.57±9.18	**0.039***	2.48; (-3.01 to 7.96)	0.376
Int n=7	30.69±8.68	28.93±10.85	0.355		
Thoracic range α3					
Con n=6	58.63±10.06	57.52±14.28	0.873	3.95; (-14.73 to 22.62)	0.679
Int n=7	54.57±14.38	57.40±13.00	0.662		
Full trunk flexion/extension range αfti					
Con n=6	175.02±1.88	166.88±19.33	0.168	7.08; (-8.66 to 22.82)	0.378
Int n=7	151.56±34.21	150.50±39.95	0.846		
Thoracic spinal rotation range Tr					
Con n=6	87.00±20.01	93.62±22.60	0.141	-7.79; (-19.79 to 4.21)	0.203
Int n=7	77.06±13.80	75.88±16.14	0.778		

***p<0.05** Δ=change

4.3.4.4 Thoracic spinal rotation (Tr)

There were no statistically significant between or within group differences for thoracic spinal rotation at baseline, weeks 8, 8b and 12. Full results, b-8, are presented in Table 4.27. Full results, 8b-12, are presented in Table 4.28.

4.4. Association between subjective and objective results

There was a strong association between subjective (from the interviews and reported in Chapter 5, Results 2) and objective (primary and secondary outcomes) results that were comparable at week 8. Some examples follow.

One participant (H15) reported that both she and her husband could see the reduction in the swelling of her affected arm, which was supported both by her improved *L-dex* and *arm volume* of lymphoedema scores. She further commented how much more easily she could move between her ribs and hips. This was supported by her improved range in *lateral flexion* for *thoracic distal curvature* (βdc) from baseline to week 8. These improvements are presented in *Figure 4.14* below.

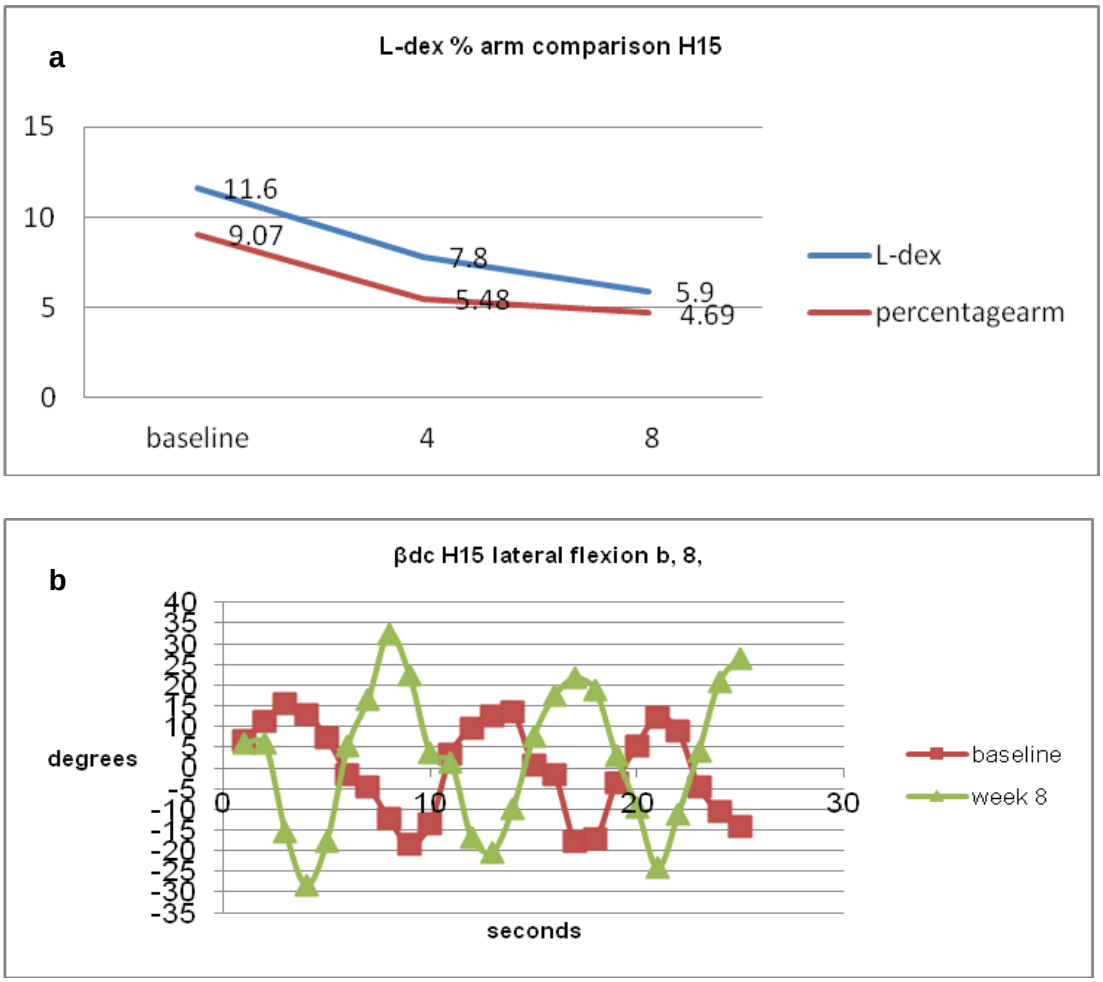

Figure 4.14 Improvements H15, b-8: **a**. *L-dex* and *% arm volume* of lymphoedema **b**. *lateral flexion* of *thoracic distal curvature* (βdc).

Another participant (L01), who had had lymphoedema for 20 years, stated that she could close the garage door for the first time in 20 years, an action which requires *flexion* of both arms, *extension* of the thoracic spine and *grip strength*. Her improvements in shoulder ROM, *grip strength* and *thoracic range* in spinal *flexion/extension* (α3) are illustrated in *Figure 4.15* below.

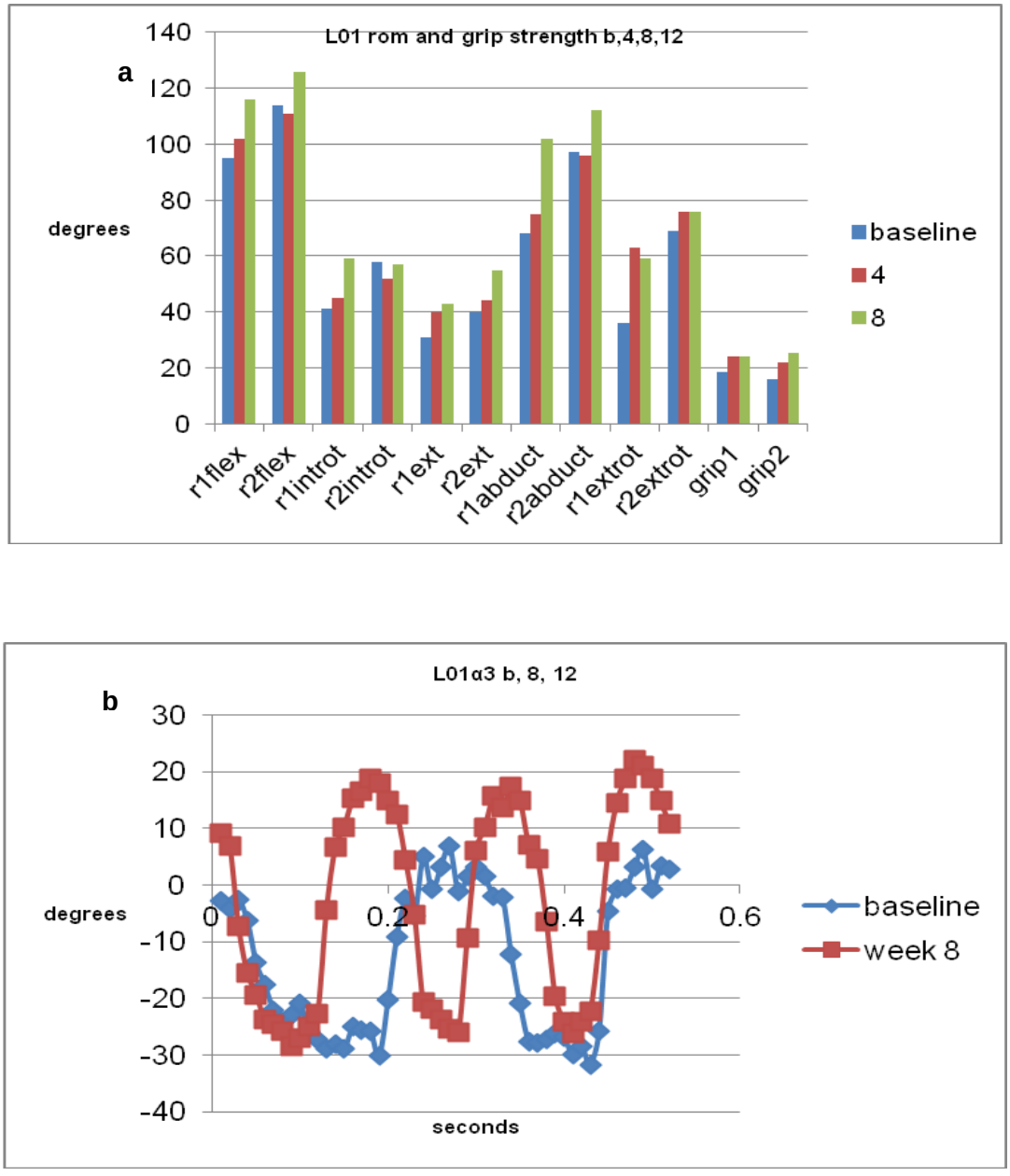

Figure 4.15 Improvements LO1, b-8: a. shoulder ROM and *grip strength* b. *thoracic range (α3)* in *flexion/extension.*

A third participant (L011) stated that, when her hand swelling (lymphoedema) decreased, she could hold the girth of her horse tighter (*grip strength*). This observation was supported by her objective results, as illustrated in *Figure 4.16*. This pattern was also seen in the group results. There appears to be a connection between reduced *hand volume* of lymphoedema and increased *grip strength* and vice versa.

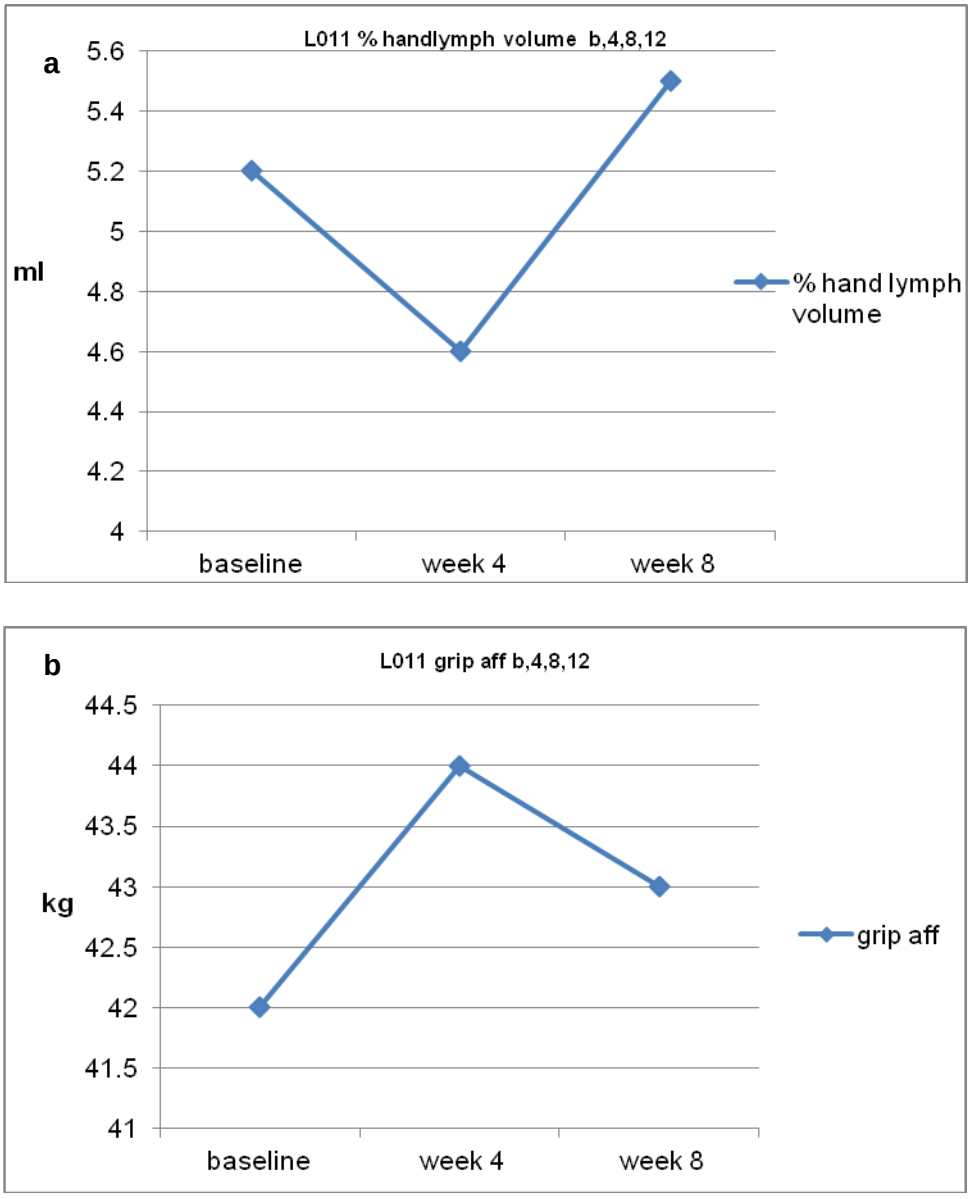

Figure 4.16 Improvements L011, b-8: **a**. *hand volume* of lymphoedema **b**. *grip strength.*

Finally, one participant (LO2) told of significant changes in her QOL and their positive ramifications on her life, as reported in the theme Individual Journeys (Chapter 5, Results 2). Her remarks were supported by her QOL scores, as illustrated in *Figure 4.17* below.

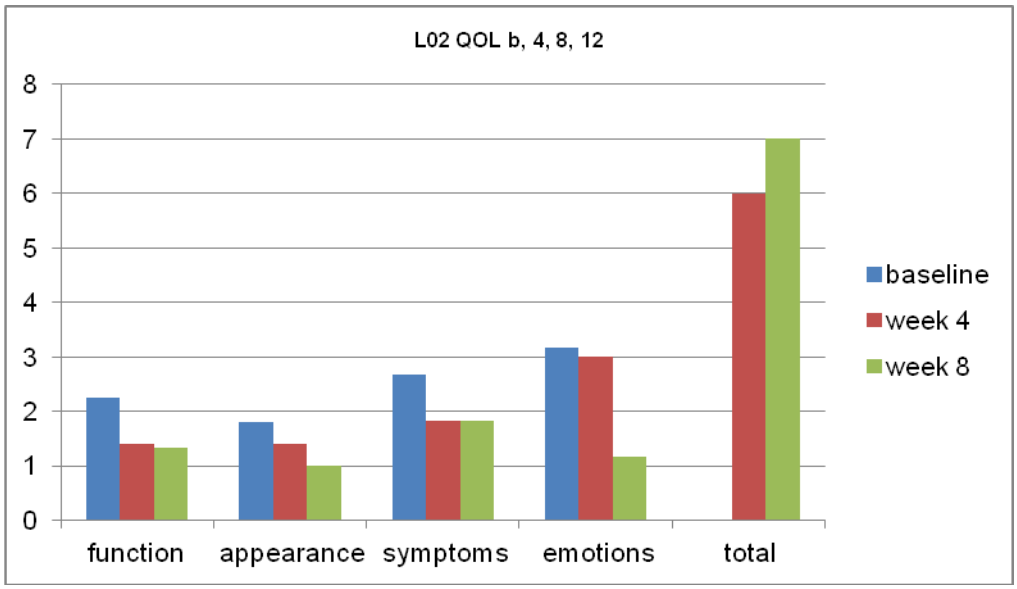

Figure 4.17 Improvements in L02, b-8: QOL.

(Note the lack of bar for *total QOL* at baseline, reflecting her "0" score).

4.5 Conclusion

Demographic and medical information was based on the women whose results were analysed from b-8 (n=23) and revealed that the women in the trial were similar between groups in the variables measured. Significant differences were in BMI (p=0.023), which was higher in the intervention group (although high in both groups), and in the amount of participation in exercise classes, which was higher in the control group (p=0.006). Other noticeable group characteristics were the high rate of invasive carcinoma, which meant that most women had mastectomy and axillary clearance, and the adverse effects that women experienced from chemotherapy and radiotherapy. Results were analysed in two sections due to the illness and absence of four women at the week 12 measurement. Hence, results were presented as b-8 (n=23) and 8b-12 (n=19). A sub-group of women with L-dex>10 (n=8) was analysed, but as the results were reflected in the results for the whole group, only p values for significant between group results were given.

From b-8, lymphoedema was not exacerbated. Although there were no significant between group results for *L-dex* or *arm* and *hand volume* of lymphoedema, the intervention group had a significant reduction in *arm volume* at week 8 (p=0.029). For the other primary

objectives, there were significant between group results in favour of the intervention group at week 4 for the degree of *pain limiting activity* (p=0.035) and at week 8 for a reduction in affected *upper arm tissue density* (p=0.050) and for an improvement in the QOL sub-scale of *symptoms* (p=0.038). The intervention group results also showed reduced *tissue density* of the affected *chest* (p=0.044), which became lower than the non-affected *chest*.

From 8b-12, there was a significant between group result in favour of the control group for *arm volume* of lymphoedema (p=0.032), due to a significant increase in volume in the intervention group (p=0.026). Both group results showed significant improvements in *tissue density*. Finally, while the control group improved significantly in the QOL sub-scale of *symptoms* (p=0.027), the intervention group declined significantly in that of *function* (p=0.026).

From b-8, secondary objectives resulted in a significant between group result in favour of the control group for shoulder ROM in *flexion* (p=0.011) and *abduction* (p=0.049) for the non-affected arm. Significant improvements in various actions of shoulder ROM were observed in both groups. At week 8, the improvements in the control group were parallel between the affected and non-affected arm. In the intervention group, the ROM converged between the affected and non-affected arms, especially in *abduction* and *flexion,* resulting in symmetry between arms.

Strength measurements produced no significant between group results, but some significant within group results. The most sustained was the significant improvement at both week 4 and week 8 in *abduction* for the affected and non-affected arms in the intervention group.

From 8b-12, significant between group results occurred for shoulder ROM in *internal rotation* for the affected arm (p=0.001) due to a significant reduction in the intervention group (p=0.005) and also in strength of *pectoralis major* for the non-affected arm (p=0.002), due to a significant reduction in the intervention group (p=0.004). *Grip strength* of the affected arm produced a significant between group result (p=0.010) in favour of the intervention group, due to a significant reduction in the control group (p=0.002).

From b-8, spinal mobility in the self-nominated sub-group resulted in a significant between group result for improvement in *pelvic obliquity* (p=0.023) due to a significant improvement in the intervention group (p=0.001). A number of changes occurred in both groups in how they moved in *lateral flexion* and *flexion/extension*. Most of these changes were sustained until week 12.

The amount of physical activity was higher in the control group at a weekly level and similar between groups at a daily level, though both groups fell into the medium level for both weekly and daily activity.

Examples of the association between objective and subjective results were given, linking this chapter to the next.

In summary, from b-8, lymphoedema was not exacerbated and *symptoms* and *tissue density* improved in the intervention group. Further, results showed that the intervention group became similar between sides in shoulder ROM and strength, and improved in *pelvic obliquity* for lateral flexion of the spine. Many of these improvements, however, did not continue until week 12.

Interpretation of these results is presented in Chapter 6, Discussion. The results of the qualitative data collected from the individual interviews with the women in the intervention group are reported in the next chapter.

CHAPTER FIVE RESULTS 2

This chapter will present the results from the interviews conducted at week 8 immediately following the yoga intervention. Information from participants' logbooks was also collated. The results are reported as the themes and sub-themes that emerged, with illustrative citations from the interviews and logbooks.

The aims of the interviews were to:

1. Collect comprehensive qualitative data which would produce a complete picture of the experiences of the participants during the eight weeks of the yoga intervention;
2. Obtain direct and honest opinions of the various facets of the yoga classes while they were still fresh in the participants' minds and find out what had worked and what could be improved;
3. Ascertain the participants' views of the home-based section of the trial: whether the content of the specially made DVD was useful, comprehensible and the right length; and whether the overall commitment had been too onerous;
4. Compare qualitative and quantitative data, to determine the degree to which associations could be made.

All women who attended the yoga intervention were interviewed (n=15) as, in spite of illnesses that prevented some women's scores being recorded for the quantitative results, they had conscientiously participated in the yoga class and home-practice DVD and their input was thought valuable.

Following verbatim transcription of the interviews, the text data, along with pertinent information from the logbooks, was analysed by two researchers working independently and meeting regularly. Using an iterative-thematic approach, six major themes were identified: (1) Physical Outcomes; (2) Mental Health Outcomes; (3) Social Outcomes; (4) The Yoga Phenomenon; (5) The Breast Cancer Experience; (6) Individual Journeys. Each theme was further divided into various sub-themes. For each theme and sub-theme, the number of respondents and responses was noted, to indicate the relative importance of the data. This information appears in Appendix D.

The theme Individual Journeys records the quite extraordinary subjective changes reported by nine women during the eight weeks of the intervention. Statements like "I am now back in control of my life" (L08), "I am a totally different person" (L02) and "I can hold my grandchildren for the first time ever" (L01) clearly revealed the powerful impact of

participation. A summarised version of one of these journeys is included here, with five full stories in Appendix F.

5.1 Themes

5.1.1 Theme one: Physical Outcomes

5.1.1.1 Lymphoedema

Determining the effect of yoga on lymphoedema levels was a primary objective of this study and all women (n=15; 100%) commented on it. Eleven women (73%) mentioned a sustained improvement in their affected area since starting the yoga and four of these spoke also of the tissue softening. A typical comment was: "My underarm area, which a build-up of fluid usually makes tight and sore, has been a lot more flexible." (L08) Other improvements mentioned included a softer, less oedematous hand (noticed by colleagues at work), an absence of numbness, softer shoulder tissue and less fluid, observed by three women (20%). One participant said: "I'm convinced now that the yoga is improving my shoulders and thoracic spine and the lymph drainage" (L01), while another was aware of the lymph flowing from her lower arm to her shoulder girdle. Arm improvements in three women (20%) were such that they did not have to wear their compression sleeve as often.

The logbook of one participant, in which she had made 13 separate comments about lymph flow while doing the yoga at home, revealed that the *swiping* and *archer postures* and the *bent elbow* and *arm rotations* were the most effective yoga movements for increasing the flow of lymph. She also stated: "I definitely feel most flow when lying down on the floor, legs bent to the side; I can't really notice it when sitting or standing." (H17) She was also conscious of lymph movement during the *alternate nostril breathing*.

While the prime focus of the trial was on arm lymphoedema, one participant who also has breast lymphoedema reported: "My breast is not swollen in the way it used to be. There's a lot less fluid there, because I was retaining a lot of fluid. Where the scar is on my breast – because of all the yoga and the DVD I am doing at home – my scar is a lot softer." (L02)

Four women (26%) reported that "there were certainly no adverse effects in either sensation or volume as a result of the exercises" (H2) and "I have not experienced any pain, strain or discomfort throughout the trial period, and no swelling of my affected arm or visible adverse reaction." (L09) The woman with the highest level of lymphoedema felt the "status quo has been maintained, and it hasn't got any worse." (H2)

These observations were substantiated by the women's objective scores in both lymphoedema and tissue density.

5.1.1.2 Pain

A reduction in lymphoedema-associated pain was reported by five participants (33%), one in her elbow (relief noticed as early as the fifth day of the DVD practice), one in the back of her hand, one in the pectoral muscles and two in the affected arm: "My arm gets tight and aches, but it's just felt a lot better since I've been doing the movements" (L08)and "I haven't had the pain in my arm that I used to get." (H14)

Five others (33%) commented that they only felt pain when they did something excessive, and this had not occurred during the yoga. Two others said they currently had pain, one saying that it was a result of aromatase inhibitors, and the other for no apparent reason in her back. (One week later, she was diagnosed with secondary breast cancer in her bones).

5.1.1.3 Heaviness

Eight participants (53%) were conscious of a lack of, or reduction in, arm heaviness from lymphoedema. One woman expressed her relief in the following way: "When you go through the yoga, if you can just lie there at the end, there's no heaviness, the lightness is just absolutely wonderful, and you'd like to actually stay there, in that place." (L03)

5.1.1.4 Arm range of motion

One of the secondary objectives of the study was to explore the effect the yoga would have on the ROM of the affected arm. Seven participants (47%) reported sustained improvement around the shoulder area, which led to functional improvements such as being able to reach and stretch, and perform everyday tasks that had been impossible since the advent of lymphoedema. The woman who had lymphoedema the longest, was able to support her claim that "I've got much more movement in my shoulder than I ever have had in the last 20 years" (L01) by opening and closing her garage roller-door for the first time. This was further reinforced by her scores for shoulder ROM in flexion, for grip strength and for spinal ROM, which are presented graphically in Chapter 4, Results 1, *Figure 4.15*.

5.1.1.5 Strength

Four women (26%) had become conscious of greater body strength. The most touching example was a 64-year-old grandmother who, for the first time, felt strong enough to hold her grandchildren. Improvements in core strength ("I definitely think my core strength has improved, which is sort of amazing when you're doing such small, gentle movements")(H14) and abdominal strength were reported by two other participants.

5.1.1.6 Flexibility/Mobility

Greater flexibility, increased suppleness and improved mobility were highlighted in a general way by three participants (20%). Two others were more specific: "When I bend, I can actually touch the floor now, which I haven't been able to do for a long time" (L02) and "I

have felt less tightness and better movement in my arm and on both sides of my chest after doing the DVD." (L03)Another participant found great relief when a front-back scar from a kidney operation 10 years earlier lost its ongoing tightness. This improved flexibility is represented graphically in Chapter 4, Results 1, *Figure 4.14*. These observations were substantiated by improvements in the women's scores in shoulder or spinal mobility and tonometry.

5.1.1.7 Posture

An improvement in posture, whether sitting, standing, moving or driving, was noted by eight women (53%). "The morning after doing the evening yoga," said one participant, "my back would be a bit straighter, my shoulders in the right position and I felt as though I was walking taller." (L03) Another commented: "I noticed I was tending to slouch a bit. I was conscious of it, which is half the battle… Keeping my posture definitely helps my athletics." (H14) All eight women were determined from now on to keep their body more upright, instead of slouching and slumping. In a series of specific comments about the yoga, one woman wrote: "I now have to consciously ensure that my weight is spread evenly when standing, knees slightly bent, pressure evenly on all points of the foot, especially the heel; I normally tend to stand with knees quite stiff when not moving, so this has been good for me." (H1)

5.1.1.8 Other physical outcomes

Ten women (67%) reported additional physical outcomes. One participant spoke of the noticeable improvements in her back and neck. Relief too for the woman who, four weeks into the trial, was able to stop taking constipation medication.

Diaphragmatic breathing was credited by one woman for the resolution of her incontinence problem, which had begun with her breast cancer and Tamoxifen treatments. An email sent one month after the conclusion of the trial advised that "when I stopped doing the daily yoga practice, my incontinence increased – back to where it was pre-trial. So, it is clearly worth doing. I believe it's the diaphragmatic breathing that's the key." (H17)

Yoga also helped with the asymmetry often felt by women with BCRL: "The yoga gave my body a chance to even itself up." (L03) Other physical outcomes mentioned included one example of weight-loss (noticed by people at work) and two examples of a large increase in energy levels.

5.1.1.9 Development of physical awareness

Yoga, with its strong emphasis on physical and mental awareness led all 15 participants (100%) to realise just how little they knew about how they moved. This awareness was of great interest to these women and emerged as one of the major outcomes of the trial. "I've got a lot more physical awareness" (H14) and "a total awareness of the effect of the yoga on my

body" (L011) were frequently mentioned. One participant expressed this idea particularly well:

> *I've found the yoga has made me very, very much more aware of how everything actually operates. And so, instead of just doing something, the exercises that we've been given, I actually have put some thought into what I'm doing and how I'm doing it, rather than just barging in with no thought at all.* (H2)

This increased awareness was also felt during the yoga class, with women's comments revealing a new knowledge about moving from the side rather than from the shoulder, releasing face tension, being aware of the centre of gravity and consciously relaxing.

Physical awareness was closely related to mental awareness; for example, two women commented that they now knew when they were overusing their affected arm, while another realized that she ignored her affected arm and did everything with her non-affected arm. Further, three participants stated the necessity for greater personal vigilance, whether it be "doing the DVD in a slow and steady way when the humidity makes my arm heavy" (H15) or keeping "my *sankalpa,* my promise to myself, getting rid of this extra weight because that's what my lymphoedema needs" (H4) or simply "looking after myself, particularly my arm, a lot more." (H3) Another woman noted a new awareness of how her ability to hold her horse's girth was related to her hand volume of lymphoedema (represented graphically in Chapter 4, Results 1, *Figure 4.16*), and another acknowledged the relationship between her sleep patterns and her level of lymphoedema.

5.1.2 Theme two: Mental Health Outcomes

5.1.2.1 Development of mental awareness

Twelve participants (80%) reported a heightened mental awareness. One woman mentioned her ability now to consciously shut out unwanted thoughts; another her recognition that stress levels were mounting; a third her desire to find time for herself without feeling guilty: "I have stopped rushing home every evening after work. I actually feel ok to go somewhere else now. I have gone out to dinner and I've felt good." (H3) Another participant stated that she now realized going to the cupboard for a snack was detrimental to her decision to lose weight. Finally, one woman stated:

> *Mentally, I've been fascinated because I never realised I had such a disorganised brain. I always thought I was a person who was able to focus and achieve, but I've discovered I've got a brain that drifts off like a butterfly and it cannot be brought to hold focus for very long, with the attention-span of an ant!* (H2)

Four other women (26%) made unprompted comments on their ability to stay focussed, to think more lucidly, and to plan better: "The necessity to focus on the yoga has helped me to clear away anxiety and daily pressure" (L011) and "I've actually been able to plan my

days better, be more precise, not um-and-ah so much about what I need to do and what has to be done." (H4)

5.1.2.2 Overall wellbeing

Twelve participants (80%) volunteered an opinion about their improved wellbeing. A woman who had lived with lymphoedema for 20 years stated: "Something in my overall sense of wellbeing has taken place in this past couple of months, as much as anything I can identify physically." (L01) Similarly, a woman with a more recent diagnosis reported: "My general wellbeing has benefitted very, very much." (L011)

5.1.2.3 Equanimity and Calmness

The yoga experience created greater equanimity in participants: "The yoga makes me feel so much more at ease about everything; it really flows into all areas of my life" (H3) and "Being relaxed, thanks to the yoga, carries over into a feeling of contentment. And just being happy with life the way it is… you just sort of accept what you've got and be grateful." (H11)

Seven participants (47%) reported a reduction in stress, anxiety, worry and depression. Three commented on stress reduction ("The difference from day to day is phenomenal") (L011) and related it to doing the DVD. Another woman felt on top of her "worry-wart" thoughts, particularly those relating to her breast cancer: "It's made me think more outwardly and stop worrying about every little medical thing and every little aspect of my body that's affected by the cancer. The yoga has taken that away from me." (L08) One person spoke of the depression which she was suffering at the outset of the trial and of the profoundly positive effect the yoga had on her mental state. Her objective QOL scores supported her comments (represented graphically in Chapter 4, Results 1, *Figure 4.17*).

Calmness was particularly evident, with all 15 members (100%) expressing feelings of composure, relaxation and contentment. Some (n=6; 40%) talked of the calming influence felt during the actual yoga classes. Others (n=9; 60%) recalled their home DVD sessions as a frequent source of relaxation, with one participant noting this19 times in her logbook, and another making 10 references to a "complete tension release", including a plaintive "I wish I could stay this relaxed!" (L03) The DVD was also used outside the strict framework of the trial. Whenever one woman wished to relax she just did the *yoga nidra.* Another participant, after three days of typing an assignment on her computer, decided to do the DVD much earlier than normal: "And it was just what I needed to bring balance back into my life." (H17)

5.1.2.4 Optimism and Self-effectiveness

Six women (40%) used the words optimism and hope, which they derived from being able to do something to help themselves, as well as from being inspired by the other women's stories. They felt the emergence of a positive outlook ("There just seems to be a flow-on effect of positiveness") (L01), a new buoyancy ("I now look forward to things and I'm

a lot more motivated") (L02), greater self-confidence ("It just makes me feel more confident about the future") (L09), reduced self-criticism ("Now I say to myself, don't be so self-critical, just get on with it, don't be stressed by it")(L011) and with that, less concern about body image ("I feel like my convoluted arm doesn't really matter") (L08). Comments summarised by one participant who said: "It's had a profound impact on my sense of self." (H2)

5.1.2.5 Time for Self

Twelve participants (80%) spoke with great enthusiasm of the "quiet moment for yourself" (L011) which they had to put aside for the daily yoga: "I think it's really important that we should all, every now and then, give time to ourselves, and the yoga has made me experience that wonderful 'time out' for myself." (H11) The knowledge that each day would have its yoga slot, reserved for herself, no matter how much was going on, was of great psychological benefit. In the course of the intervention, the logbook entries for the DVD moved from **the** yoga to **my** yoga, and the slot became, for example, **my** Thursday morning.

An identical positivity was felt on the day of the yoga class: "It was a change to get out of the house and do something just for me" (L02) and "I looked forward to coming out, having a break and doing something for myself." (H4) The underlined expression was found in 11 interviews (73%), indicating just how significant this time for self was in their week, even when it meant busy family preparations before coming to yoga or a later than normal drive home.

5.1.2.6 Discipline and Control

Four women (26%) also found benefit from the self-discipline required to attend a weekly yoga class and do the daily practice by DVD. One woman, when asked what was the greatest overall benefit of the yoga, replied: "Just that discipline of needing to do the yoga, knowing that I would enjoy that calmness that comes over you when you're actually doing the activity." (H1)

Five participants (33%) were happy that the yoga intervention had restored a feeling of control over their lives. For one, the experience was immediately so positive that, within the first two weeks, she made the decision to stop taking the anti-depressant medication her doctor had just prescribed. For another, this was a positive outcome after the years of breast cancer and lymphoedema procedures and treatments, during which "you don't know much about what's happening, you feel like you're in a boat that's being buffeted around, you can't really do what you want, you just feel like the whole thing's taken charge of your life." (L08) The yoga, however, was something she could *choose* to do herself and to help herself, without having to listen to the opinions of others. In the case of a third participant, this control manifested itself in what would be considered a stressful circumstance. On the way to hospital for surgery, she remembered that there were a few problems at work. Calmly, she phoned her boss, explained the situation and laughed when the boss replied: "Oh, I'll get

straight on to those. Good luck with the operation." She ascribes this new composure to the yoga, for "normally, I would have gone 'panic attack'." (L03)

5.1.2.7 Sleep

Improved sleep patterns were reported by nine participants (60%), with a typical comment being: "Since I've been doing the yoga, I find that I'll go four or five nights in a row before I hit a bad one, instead of being 'one up, one down' as before." (H2) Some (n=3; 20%) reported a clearer and more relaxed mind by "not worrying, not reviewing the day as it was, or thinking of what I have to do tomorrow" (H4), allowing them to fall asleep more quickly. Others (n=6; 40%) reported long, undisturbed sleep: "When I finish the practices, I go to bed and I sleep right through. I don't even have to get up to use the bathroom or anything." (L02) The routine of doing the yoga just before going to bed seems to have been of great benefit, as another participant volunteered: "Despite the other things that keep me awake – blocked nerves, tingling, nerve impingement of my good arm – it was good that those nights when I did the yoga late, I could sleep better." (H11)

The self-assessed LYMQOL scores for sleep quality of the six participants (40%) not included in the above results reveal that none had any real sleep problem at baseline, weeks 4 or 8.

5.1.3 Theme three: Social Outcomes

5.1.3.1 Relationships

Observations were made by 11 participants (73%) about their improved relationships. Five women (33%) commented on increased tolerance and patience in their dealings with family: "I'm much less volatile with my girls who really know how to push my button" (H4) and with people in general: "I don't get irritated as much… I now find it's easier to just let things go with the flow, rather than bearing grudges or getting resentful." (H2)

A greater sociability was mentioned by three other participants (20%), one relating how she and a friend now phone each other, walk together, talk together, because "keeping in touch with somebody makes all the difference." (L02)

One woman, having acknowledged that the yoga had made her "more relaxed about sharing", felt comfortable enough to speak, in a very moving way, of her husband who for the previous two years had been suffering chronic depression: "The yoga and the DVD relaxation have helped me a great deal; enabling me to cope with him has been a big, big benefit." (L01)

The yoga engendered in the women feelings of frankness ("I just say things if I want to say them now, whereas before, I got all churned up") (L03), open-mindedness ("It has helped me to find all the good things in people") (H11) and altruism ("A girl-friend's struggling with

mental illness at the minute and when we were doing the candle meditation the other week, I thought: 'This is what she needs', so I've been encouraging her a lot to get into yoga"). (H3)

The women also told how their family members had commented on the effect of the yoga. One daughter remarked on her mother's improved spirit and three husbands noticed an increased calmness, the clearest example being the following anecdote:

> *My husband and I were in the kitchen and I was venting my spleen about something and he looked at me and said: 'You haven't done your yoga today, have you?' And I thought: 'Don't you start! Yoga, what's this got to do with yoga?' Then I realised he was right. He actually noticed the difference in me.* (L011)

5.1.3.2 Group Dynamic

All 15 participants (100%) spoke at length and with great enthusiasm about the pleasure, knowledge and motivation derived from the company of women with the same problem and similar experiences. Sharing both their medical ordeals and their encounter with yoga became a "really powerful experience" (L01) for one, and for another, "it made me realise I was not the only one; the others kept me going." (L09) Sometimes, the outcome was quite unforeseen: "I didn't expect to feel any similarities but I know now that sharing with a group of women in that way had a very big impact on me." (L011)

The value lay in different aspects of this sharing process. Some appreciated the liberating opportunity to simply talk and tell their tale; in the words of one woman: "It was lovely to see how the personalities just opened up to each other with their stories." (L01) Others valued listening to what others said: "Just hearing how the yoga affected them, whether it made them feel better, or bad, or whatever." (H11)

Despite one participant saying "part of me doesn't like listening to other people's experiences of cancer because it's something I'd like to move on from, it's not the club I want to be in", she went on to say "the good thing is we all understand our limitations." (H9)

Several women spoke of the comfortable ambience and high level of trust within the class, which allowed such an honest and uninhibited exchange. Particular beneficiaries were the participants who did not join any support group at the time of the breast cancer. One woman admitted: "Having contact with similar women has definitely been a positive. At the time of my illness it was not something for me, but definitely now, yes… and discussing things with other women, it's been terrific." (H3) A second, while acknowledging the unfailing support she had received from husband, family and friends, commented: "I didn't think I needed to join a support group but sometimes I wish I had, because I've just realised through going to the classes how much better it makes me feel to know that other people go through the same things and hear about the different ways they manage." (L08)

Women supported each other and gained hope: "One person… her fluid retention had gone down and just knowing that hers could go down over the course of a few weeks gives me hope that maybe my fluid will find a way down too." (L03)

5.1.3.3 Reason for participating and commitment

When explaining why they had volunteered to participate in the trial, 13 women (87%) manifested a strong social conscience in their obvious desire to help others. One participant, making it her very first point, emphasised how wonderful it would be if something else were found that could reduce/control lymphoedema, give other women more confidence about their outcomes and improve their QOL. One woman was particularly mindful of those living outside large urban centres: "The yoga would be marvellous, especially for women in more remote areas. It must be so hard for them, driving so far to get treatment. They must feel very isolated." (L08)

These Tasmanian women were very keen to be actively involved in this study, even though quite a few (n=6; 40%) admitted they had never been attracted to yoga beforehand, seeing it as "airy-fairy" (H1) and themselves as "very practical, very sceptical." (H2)

The powerful altruistic motive for participating was accompanied by several important observations about the perceived lack of support and information about lymphoedema given to some women after surgery: "You seem to be given a bit of a pamphlet and unless something goes majorly wrong with your arm, no-one cares" and "I think I went to two or three physios and 'well, everything's all right now, bye bye'… I got the impression that there was really not much treatment or anything like that available, I just felt I was left on my own" (L08) and "In my experience, the average physio doesn't have the background in lymphoedema to be able to give you the right exercises, and a lot of doctors don't have that commitment either." (L09) Seven women (47%) referred to the expense and distance involved when travelling for treatment and stated that the drive home caused their arm to swell again, one woman even affirming that this was the reason she would not get further treatment. Generally, women felt that there needed to be more options. As one participant put it: "Since some medical authorities underestimate the value of complementary and alternative therapies, more trials of this nature would make women with lymphoedema more aware of alternative self-management options." (L011)

A strong commitment was shown by all participants (n=15; 100%) throughout the intervention (as evidenced by the compliance figures). "My commitment to helping others actually helped me to be more focussed and more committed to doing the yoga." (H14) Nine participants (60%) stated that it had been easy for them to attend the weekly classes, their comments ranging from the neutral "I knew what I was signing up for" (H9) to the enthusiastic determination never to be absent: "I would have been really disappointed if I'd missed a class. I would have hated it. I thought that was really important." (L011)

The daily home-practice was more problematic, with seven women (47%) admitting that it was sometimes a challenge to overcome family, social or work pressures, or genuine fatigue. For three of them, finding a quiet place at a quiet time had proved harder than expected; another three acknowledged a greater commitment than anticipated, two as a result of jobs acquired during the trial. Nonetheless, all 15 women (100%) did their utmost to postpone all other distractions, until the **entire** yoga practice had been done: "I was meticulous about doing the full program every day in my little yoga slot." (H2) And for those whose schedules were more flexible, typical remarks included: "There was never any question about **not** finding the 42 minutes somewhere in the day" (H15) and "It didn't really matter **when** I did it, but I **had** to do it, even as late as 11p.m." (L09) Four members of the group (27%) mentioned their "guilt" if they did not do it faithfully every day; they felt a sense of "responsibility" towards the study and its outcomes, which meant "following it through to the end and not just saying: 'Well, I can only do 20 minutes.'" (H17)

5.1.4 Theme four: The Yoga Phenomenon

5.1.4.1 Yoga Practice

i Postures/Asana

The diverse comments made about the postures included: "I think that the movements have helped me to feel better" (L08) and "I really enjoyed the yoga movements because they were so different from my usual work and housework, so I think that putting my arms, my muscles, into doing them has been beneficial." (H4) One woman expressed surprise that the postures were not physically more demanding; another was "amazed that such small, gentle movements can actually have an effect, but they certainly do." (H14) Conversely, some postures had their own challenges. One participant, when doing the DVD, had to remove her bra and prosthesis for the *swiping* actions, while two others admitted that they never really mastered the technique of *rowing*, either in class or at home.

One woman disclosed in a logbook entry that, after adopting a fairly hard and aggressive attitude in the early sessions, she had settled in to a smooth and flowing approach. A second participant had to stop herself anticipating and rushing ahead of the tape.

Nine participants (60%) spoke positively about the supplementary practices added in class. Women commented that these extra movements provided variation, a greater range, and even a feeling of "moving on a little bit from the lessons." (L01)

ii Breathing/Pranayama

Apart from the connection between breathing and postures ("I like how she said 'the time of the breath is the time of the movement and the time of the movement is the time of

the breath'") (H9), the importance of breathing was highlighted by10 women (67%) in a very general way.

Six women (40%) found the breathing practices enjoyable and effective in, for example, creating a feeling of lightness, improving incontinence and reducing fatigue. For a couple of participants with high levels of anxiety or stressed from work or family commitments, the breathing techniques were more challenging, particularly early on. It took a while for four others (27%) – up to 11 days in one case – to learn how to "breathe away" thoughts and emotions, to differentiate between a warm breath and a cold breath, to feel the breath moving in the nostrils and body and to be able to fully coordinate inhalation/exhalation with their movements.

Alternate nostril breathing produced only two remarks: "I clearly felt the lymph move with the nostril breathing" (H17) and "After this practice, I felt my jaw tension release." (H9) For one woman, the breathing in the *yoga nidra* was problematic: "When it got to the breathing part of the *yoga nidra*, I just tended to get a bit twitchy, I could feel myself tensing up a little and sometimes I couldn't finish it." (H4)

iii Mindfulness practices /Antar Mouna

Only two participants specifically mentioned the mindfulness practices used at the beginning of the session, as distinct from the breathing. One woman said:

> *It's hard to relax but I really like the aspect of trying to clear my head, because I've got so much going on with two young children, cancer… I've always got lots of things going on in my head and so it's been good to clear the mind for a period of time.* (H14)

iv Relaxation/Yoga nidra

The calming, balancing effect of the relaxation was appreciated by all 15 participants (100%), who found this opportunity to "just zone out" (H17) very beneficial: "I really did just allow myself to go in to what was happening and nothing on the outside was intruding at all." (L01)

Not allowing themselves to fall asleep during the relaxation was a challenge for many participants, both in class and at home. The opinion that "I think most of us at some stage would have nodded off in the relaxation" (L09)was borne out by comments in six logbooks.

Six participants (40%) mentioned times in their daily lives, outside the trial itself, when they consciously turned to their DVD for assistance. The relaxation techniques enabled three women to get (back) to sleep during the night. Two others found that the "structured practice" of *yoga nidra* relieved the stress and emotion that had built up: "Having to listen and concentrate on something made me relax." (H4)

One woman made reference to the first part of *yoga nidra,* known as rotation of body consciousness: "I really liked the rotation of body consciousness. I really looked forward to that part. I could sort of picture myself rocking from side to side, left-right, left-right. It's the closest I've ever got to meditating." (H4) Another said that she found it too fast, so did her own slower practice.

Comments were elicited by the visualisation part of *yoga nidra*. One self-confessed "yoga sceptic" discovered in herself "a pathetic inability to focus and visualise, although I **am** trying!" (H2) Another "not particularly 'visual' person" preferred the series of fleeting images done in the classes to the DVD's practice of visualising "a tree, plant or flower." (H1) The most imaginative visualisation left its creator feeling "very cheerful and colourful" and as a result, she was able to incorporate visualisation into her physical practices:

> *I used to visualise my lymphatic system as a web of Christmas lights, those ones you buy from Chickenfeed, with the twinkly lights embedded in a plastic tube and I added this to the exercises, so when I do the clearing exercises, I distinctly imagine the lymph cells twinkling busily up and down the network.* (H2)

5.1.4.2 The Yoga Class

During the interviews, the participants were given ample opportunity to voice concerns or make suggestions for improvement to the classes, the DVD and the overall organisation of the trial. With the exception of one suggestion about the room in Hobart ("Perhaps a more pleasant room") (H15), no other ideas were expressed.

Adjectives that recurred most frequently in the interviews to describe the teacher's (A.) personality were "calm", "friendly", "approachable", "positive", "enthusiastic" and "patient". These traits were reported by all participants (n=15; 100%) as being responsible for the close, friendly, soothing atmosphere in which the whole trial was conducted: "As a leader, she did a brilliant job. I will miss her lovely sessions." (L09) Seven women (47%) expressed their appreciation of the teacher's careful supervision and attentive correction of posture and movements. As one participant commented: "She showed great sensitivity to everybody's individual needs." (L09) Sometimes, it was a case of not moving properly: "I couldn't… I was doing this, and A. picked it up the first lesson and said: 'No, it's not about your shoulders.'" (L011) At other times, a woman's confidence would need restoring with encouragement and patience: "To see A. and speak with her, and get the feedback that what you're doing is fine, or else 'No, try this.' To have that once a week was just great." (L09)

Gratitude was also expressed for the punctual start of every class and for the time that A. always made to answer questions and discuss concerns. There was never any rush, or in the words of one participant, "nothing loud or boisterous or 'hop, hop, come on, we've got to get this done'; it was just floating!'" (L03) There was agreement among the women that the

teaching style helped to maintain their 100% dedication to the classes, the hours of measurements and the daily home DVD: "I wouldn't have kept the motivation for 8 weeks if it wasn't for those weekly sessions, and I know that for a fact. It would have waned, a lot." (L011)

No improvement to the conduct of the classes was suggested by any participant, either voluntarily or in response to a direct prompt like "Was there anything that you would like to have been different in the classes?" All 15 women (100%) were satisfied with the way the yoga classes were run.

5.1.4.3 The Home-practice DVD

All the participants (n=15; 100%) indicated that the DVD was easy to understand and follow, with clear instructions and demonstrations, the side/front double viewpoint proving particularly useful. Most women had established a routine and were familiar and confident with the practices by the fifth session, even though a couple of women noted that they found "different dimensions" (H15) and "new moments" (L09) every time they did the DVD. Those logbooks which contained detailed remarks (n=11; 73%) revealed the participants' satisfaction ("restful", "enjoyable", "balancing" were typical adjectives), accepted the 42-minute length as appropriate and expressed appreciation that the DVD took into account individual needs; for example, the use of a small rug under the back or sitting on a pillow.

There were two helpful suggestions made to improve the DVD. The first was to have the same relaxation as in class and the second to slow it down a little.

Two women with high levels of lymphoedema described in detail their daily self-management and their regular MLD, as a way of saying that they found it easy to add the daily DVD. (In fact, both of these women had 100% attendance and compliance). They, along with two other women, were happy to use the yoga DVD as another self-management tool. Conversely, one participant remarked that, along with her daily self-massage, adding the 42-minute DVD made her resent the amount of attention she needed to give to lymphoedema management.

5.1.4.4 Benefits and Future Intentions

All 15 women (100%) made positive remarks about the yoga, with one saying: "The yoga has been fabulous for me. I'm totally convinced it's worked for me" (L01); another affirming: "This has had a positive impact, physically and emotionally, in almost all areas of my life" (H14), and a third stating: "I am a totally different person." (L02)

The yoga was reported as being "fun", "interesting", "exciting", "new and different" and ultimately, in the words of all 15 members (100%), "enjoyable."

Thirteen participants (87%) indicated that they intended to continue with yoga after the conclusion of the trial. Seven (47%) were determined to do it daily, one admitting that it would certainly be a challenge without the inspiration of the weekly class, one aiming to incorporate some of the supplementary practices, one saying resolutely "I will not give up *my* yoga" (L01) and one just grateful to have found "something which is good for me and which I enjoy". (H11) Five other women (33%) talked about continuing to do the full DVD, but on every alternate day. Finally, one participant was going to include *yoga nidra* in her evening schedule.

5.1.5 Theme five: The Breast Cancer Experience

A strong theme that emerged from the interviews was the permanent presence within each woman of the breast cancer experience. Without any prompt, all 15 participants (100%) referred to some aspect of this experience. The huge changes imposed at the time of diagnosis were still real and present:

> *Ever since I was diagnosed with breast cancer… it just changes your whole life immediately, and your whole outlook on life changes… You know, life is too short and you start to think about all the things that you want to do, you should do, you need to do. And your priorities totally change.* (H11)

On a physical level, participants spoke of the "aches and pains that weren't there beforehand" (H14), of "a tender area, and a muscle tensing or something, I'm not sure of the anatomy there, what's been done after my operation, how it's all mended" (H4) and of "the exercises that the physiotherapist gave me when I had the operation and which I still do." (H2) Several members of the group (n=4; 27%) had been taking medications since their treatment and were still living with the side effects. One woman, whose surgery was 10 years previously, commented: "There are still days when it's quite nice to get under the doona and stay there and howl a bit. And I would encourage other women to do that. You do have to let go. And just feel miserable, and angry." (H15)

5.1.6 Theme six: Individual Journeys

Nine women (60%) found the experience of participating in the eight-week yoga intervention transformative to their lives and referred to a profound change that had occurred. These changes were grouped into this theme of Individual Journeys. The changes they mentioned were usually confirmed by their objective scores. The names given to their journeys summarise the key change reported; for example, My second journey, My journey to self-knowledge, Increasing my confidence and My journey to holistic health. One journey is summarised below. The full texts of this and four others are in Appendix F.

5.1.6.1 L02 Journey towards my former self

Prior to the trial, this participant "was very, very depressed, very low, run-down". During the eight weeks of the yoga, she improved physically, emotionally and socially. For example, her energy returned to the point where she no longer spent the day on the couch, she could sleep better, she had fewer symptoms of numbness and pain from lymphoedema and far more physical movement. Added to this, her personal relationships improved both at home and socially. Feeling "calmer, more confident and more relaxed", she said: "I look forward to **doing** things….I'm a lot more motivated" and as a result, she is now cooking again, pursuing her hobby of beading and walking daily with a friend. By the end of the yoga, she could affirm: "I have made gradual but continuous progress over the two months, bringing me back to the woman I was. I don't say 100% but I am almost 100%". Her scores for **all** aspects of QOL improved markedly (*total QOL*: "0" at baseline, "7" at week 8). Other objective improvements were in sensations and fatigue, spinal mobility, ROM of the shoulder and strength of the stabilising muscles of the shoulder girdle. Subjectively and objectively, her journey of returning to her former self was reflected in her words: "It (the yoga) really worked for me".

5.2 Conclusion

Class attendance and compliance with the home DVD were both very high. Strong motivation and genuine enjoyment of the trial and the yoga emerged clearly from the interviews. The biopsychosocial aspect of yoga was evident from three of the themes that were identified: Physical Outcomes, Mental Health Outcomes and Social Outcomes.

Physical Outcomes featured sub-themes referring to the physical effect of the yoga on lymphoedema and its associated symptoms, improved posture, strength and flexibililty. All participants reported the development of physical awareness, which paralleled, and was at times difficult to separate from, the development of mental awareness. Clear Mental Health Outcomes also emerged in relation to calmness, wellbeing and time for self. Social Outcomes were strong in each of the sub-themes of relationships, group dynamic and reason for participating. The overall picture that emerged was of two yoga groups which gelled well and whose members improved across many physical, social and mental health domains. Moreover, the women's strong motivation was fuelled by a deep desire to help other women with BCRL.

As the principal aim of the interviews was to collect the women's experiences of the actual yoga and DVD, it is not surprising that The Yoga Phenomenon was a major theme. High frequency sub-themes were the benefits gained and the total satisfaction with the class and DVD. The relaxation proved to be the most popular section of the class. All participants appreciated the variety and progression of the postures, as well as the individual attention

and correction. The DVD was also well-received for its length, clarity and method of illustrating the yoga.

The interviewer actively sought suggestions on how to improve the methods for future trials, and two valuable suggestions were received: slow down the *yoga nidra* and have the same visualisation on the DVD as occurred in the class. The only improvement suggested for the class was to have a more pleasant room in Hobart. As the rooms were donated in the current trial, and may be in the future, this may be difficult to remedy. Further, as the same participant commented that "the classes were fantastic", the remark about the room may be a result of the interviewer's persistence in asking for suggested improvements.

The Breast Cancer Experience emerged as another major theme. The very real, persistent experience of the emotional and physical consequences of breast cancer, irrespective of time since diagnosis, was reported by all women (n=15; 100%)

Finally, the idea of the women experiencing the eight weeks of yoga as a "journey" was highlighted by their profound observations about the changes that had occurred in them over that period, some even believing that they were a different person from the woman who had started. While not all women experienced the phenomenon to this extent, it emerged as a strong theme for those who did (n=9; 60%).

The personal and group information obtained from the interviews was at times confirmed by the objective results presented in the previous chapter. However, the interviews also gave specific information that was not gleaned from the other measures, once again emphasising the need for a variety of different measuring tools.

The next chapter will provide a discussion of the overall results.

CHAPTER SIX DISCUSSION

This chapter will commence with a discussion of the information collected from the baseline questionnaires, followed by an analysis of the significant results and trends from the primary and secondary objectives, interwoven with relevant comments from the interviews. Links will be drawn between objective and subjective results when relevant.

Data from the current trial will be compared to other relevant research in the fields of breast cancer, BCRL, yoga, and spinal mobility, in order to contextualise the findings.

A summary of feedback about the yoga classes and the effectiveness of the DVD, gained from the interviews, will also be provided.

The chapter will conclude with the strengths and limitations of the trial.

6.1 Demographics

There were two significant between group differences at baseline. The first was the higher BMI of the intervention group compared to the control group. The second was the higher participation in organised exercise by the control group.

The severity (stage and grade) of breast cancer was high in this group of women, consistent with women with BCRL in other studies (Edwards, 2000; Swenson, et al., 2009). Consequently, most women had mastectomy (18/23), axillary clearance (22/23), a high number of nodes removed (13±8.6), and many had adverse effects from chemotherapy (11/23) and radiotherapy (11/23), all of which have been reported as high risk factors for lymphoedema in another Australian study (Hayes, et al., 2008a). High BMI (19/23 women had BMI>25 and four of those BMI>30 in the current trial), being operated on the dominant side (14/23) and post-operative fluid removal (18/23) were aspects of the women in the current trial that concurred with high risk factors reported in other studies (Mahamaneerat, et al., 2008; Ridner, 2005).

The decreasing tendency to target radiation (Lee, et al., 2008) to the axilla was reflected in the lower number of women (9/23) who had radiation to the axilla or to the chest and axilla. The chest wall rather than the axilla was the most targetted area of radiation for 14 out of the 23 women. As radiation of the chest wall may be associated with breast lymphoedema (Keeley, et al., 2007), this may explain why six women in the trial also reported having breast or trunk lymphoedema.

The time of diagnosis of lymphoedema post-surgery (1.6±1.9 years; range 1 month to 8 years) was consistent with other trials (Hayes, et al., 2008a; Thomas-Maclean, et al., 2008). The

range in time of diagnosis and varying length of time of lymphoedema (range 1 month – 23 years in the current trial) are consistent with the variation in women that yoga teachers are faced with, and are reminders of the need to consider individual histories, rather than consider women with BCRL as a uniform group.

The high incidence of arthritis amongst the women in the current study has also been reported in two other studies (Dawes, et al., 2008; Ridner & Dietrich, 2008) and is well over the norm for women in a similar age bracket (Australian Bureau of Statistics, 2006). Musculoskeletal problems reported in participants in this study were lower back problems rather than thoracic spine, neck or shoulder problems. This result was different to what was expected from women who have had surgery in the breast and armpit area, although it has been reported in another study (Dawes, et al., 2008). Previously, impairment of the thoracic spine has been reported to lead to lower back problems (Edmondston & Singer, 1997) and weakened trunk activity in women who have had treatment for breast cancer (Malicka, Hanuszkiewicz, et al., 2010). There was a high self-report of allergies by 10 women (43%). Only one other study could be found (Ridner & Dietrich, 2008) that compared the self-report of allergies between women with BCRL (8%) and those who had treatment for breast cancer without developing lymphoedema (5%). Usually, lymphoedema is associated with a compromised immune system (Mallon, et al., 1997; Rockson, 2001), so this result was surprising. Co-morbidities such as these provide important background information and also require attention when providing yoga therapy to this group of women.

As in another trial, the women generally knew what made symptoms of lymphoedema worse and were careful in what they did, so as not to exacerbate the lymphoedema (Ridner, et al., 2012). They sought professional treatment when necessary. In the interviews, seven women found the distance and expense required to travel to treatment were compounded by their arm becoming swollen again on the trip home, a problem shared by Canadian rural women (Thomas-MacLean, et al., 2005; Towers, et al., 2008). As in other trials, the women reported in the interviews that post-surgery information about lymphoedema was lacking from the medical profession (Johansson, et al., 2003; Ridner, et al., 2012; Towers, et al., 2008), as was information about treatment options, including complementary and alternative medicine (Girgis, et al., 2011).

It was difficult to gauge the level of self-management being undertaken. Only five women commented that they self-massaged, though 17 reported they wore compression sleeves as a method of self-management. In the interviews, only two women, both with high levels of lymphoedema, described in detail their method of self-management, which included remedial exercises, self-massage, elevation, wearing a compression sleeve and having regular MLD. This was similar to another study which reported that higher levels of lymphoedema resulted in women devoting more time to self-management (Ridner, et al.,

2011). Unlike the women in that study, the two women in the current trial did not resent this time and further, had 100% compliance with the yoga intervention. The lack of real understanding of how much time was devoted to self-management and what methods were used has been reported from other studies (Radina, et al., 2007; Ridner, et al., 2011; Sherman & Koelmeyer, 2011).

One of the aims of the current trial was to ascertain how effective yoga could be as another self-management technique. Thirteen participants (87%) reported in the interviews that they intended to continue with the yoga DVD to some extent as a form of self-management.

This demographic information gave valuable insight into this group of women and allowed the intervention and measurements to be conducted safely and efficiently, while remaining sensitive to women's individual physical and mental status.

6.2 Diagnosis of lymphoedema

All women in the current trial had been diagnosed clinically with secondary arm lymphoedema by professional lymphoedema therapists. Until the hire of the equipment for this trial, there was no BIS equipment in Tasmania, and so lymphoedema was, and continues to be, diagnosed clinically. Measurement by BIS at baseline revealed eight women had L-dex>10, which is considered by many to be an indication of lymphoedema. However, as diagnosis results vary depending on the method used, the current trial followed the recommendation of other researchers that a number of measures be used (Piller, 2007; Ridner, et al., 2007). Variations between scores for L-dex and arm volume in the current trial were at times substantial, as was the case in another study (Box, et al., 2002a), and so both measures were warranted.

6.3 Level of activity

Although not statistically significant, the control group had consistently higher levels of weekly physical activity throughout the trial than the intervention group, a difference particularly pronounced at weeks 8/8b and 12. This, along with the significantly greater attendance at organized exercise classes and the resumption of these exercise classes at about the same time as the commencement of the yoga intervention, may have impacted on the results of the control group. For example, the control group had a higher number of significant improvements in shoulder ROM for both arms than the intervention group from b-8 and generally higher scores in ROM of the shoulder and spine and in strength measures throughout the trial.

6.4 Primary outcomes

As this was the first eight-week trial on the effect of yoga on women with BCRL, it was imperative to evaluate the effect of the yoga intervention on:

i. the actual level of lymphoedema, tissue density, and sensations, pain and fatigue and the degree to which they limited daily activity;

ii. QOL.

6.4.1 Lymphoedema levels

Lymphoedema, measured by L-dex and arm volume, was not exacerbated during the current trial, which provides further support for the use of supervised physical therapy for women with BCRL, as has been recommended in systematic reviews of the effect of exercise on BCRL (Cavanaugh, 2011; Chan, Lui, & So, 2010; Kwan, et al., 2011). The virtually unchanged L-dex scores were consistent with those of a 12-week combined aerobic and resistance intervention for a group of women (n=32), many of whom (n=12) had lower levels of lymphoedema (Hayes, Reul-Hirche, et al., 2009), and a 17 week gentle exercise intervention (n=32) (McClure, et al., 2010), as was the case in the current trial. In comparison the significant improvement in arm volume in the intervention group at week 8, but not week 4, may indicate that eight weeks of yoga can reduce volume of lymphoedema. The significant increase in arm volume at week 12 in the intervention group, which led to the significant between group result, may further indicate that improvement is dependent on ongoing participation or that a longer intervention is required to sustain the improvement. In a four-week daily *tai-chi* trial (Moseley, et al., 2005), there was a strong trend towards a volume reduction which may support the notion that eight weeks are needed. None of the abovementioned trials reported follow-up measurements.

Only one woman in the intervention group thought her lymphoedema level was increasing during the trial. When measured, she had, in fact, decreased in both volume and L-dex scores and was reassured she could continue in the trial safely. As with a similar situation in another trial (Hayes, Reul-Hirche, et al., 2009), we surmised that, had this not been a trial, she may have left the class.

Women with BCRL have to monitor and be aware of changes to their affected arm that may indicate an increase in swelling or an infection, which require treatment, so any concerns they have need to be taken seriously (Moseley & Piller, 2007a). Apart from the one woman mentioned above, the interviews revealed a high level of awareness of the connection between the level of lymphoedema and the degree of associated sensations. Subjective remarks matched the objective scores for arm or hand volume and for reduction in pain and heaviness (as reported in Chapter 5, Results 2). This may be a result of the increased physical (15/15) and mental (12/15) awareness that was reported in the interviews. The association between the development of awareness, that is considered an important goal of yoga therapy (Evans, et al., 2009; Saraswati & Stevenson, 2010), and recognition of how sensations indicate actual changes in lymphoedema levels should be considered in

future research. However, a trial of longer duration with larger numbers would be required to monitor such awareness.

Only one woman in the L-dex>10 intervention sub-group did not improve in either L-dex or arm volume, and subjectively reported in her interview that the "status quo" had been maintained. She had the highest level of lymphoedema in the intervention group and was 100% compliant in class attendance and DVD participation. She was one of only two women who reported a thorough daily self-management program. All this may indicate that in her case, an optimal stage of lymphoedema management had been reached and that no further improvement was possible. She is included here as a reminder that not all participants, despite high compliance, will improve.

Levels of hand volume showed little variation in either group, except for the unexplained, improved group mean in the intervention group at week 4. As presented in Chapter 4, Results 1, there seemed to be an association between decreasing hand volume levels and increasing grip strength and vice versa. Given the difficulty some women in the current trial reported in their baseline questionnaires in using their hands for grip, such as is required in knitting, using scissors, holding a pen (8/23) or holding tightly (7/23), this relationship between hand volume of lymphoedema and grip strength may be worth pursuing in future trials.

In summary, levels of arm and hand lymphoedema were not exacerbated during the yoga intervention. Mean arm volume decreased by week 8 in the intervention group, but this was not maintained at week 12. There was a high association between subjective remarks and objective scores in all but one woman.

6.4.2 Tissue density

At week 8, there was a significant between group reduction in tissue density (fibrosis) in favour of the intervention group for the affected upper arm. The intervention group also improved significantly for the affected chest, where the score became lower than that for the non-affected chest.

Fibrosis is often described as a feeling of tightness in the chest or in front of the shoulder (Brennan, 1998; Lauridsen, et al., 2008; Yang, et al., 2010). A reduction in tightness in their chest or arm area was mentioned by eight women in their interviews and a further three reported a softening of their hand. Only one woman commented that her shoulder felt tighter, and this despite the fact that all her tonometry scores actually improved. This was the same woman who felt that her lymphoedema status had worsened. However, she also reported that, by doing the yoga daily, she was using her arm more than usual and perhaps developing muscles, which may have led to the altered sensations.

The yoga intervention focussed on the repetition and coordination of physical movements based on ROM of the shoulders, spine and whole body, leading to a gentle

rhythmic stretching and compression of the skin tissue, particularly in the arms, chest and upper back. It was predicted that these movements would act in a similar way to the gentle arm opening and closing exercise of a *tai-chi* trial for women with BCRL (Moseley, et al., 2005), which reported a significant improvement in tissue density in the chest in the intervention group, both as a group and in comparison to the control group. The researchers suggested that the improvement in chest tissue density may have been a result of the movement of the pectoralis major helping to loosen fibrotic tissue and improve the quality of underlying connective tissue. As both the *tai-chi* and current trial focussed on combining the physical movement with long, slow breathing and breath retention, it may be a combination of the movement with the breath that reduced tissue density in both studies.

While it has been surmised that reduction in tissue density may improve lymphangiogenesis (Piller, 2007) and so improve both vascular and lymph flow (Brennan, 1998), it is difficult to ascertain if or precisely how this occurred. The affected arm volume of lymphoedema decreased significantly in the intervention group at week 8, reflecting a possible improvement in lymphatic flow. This was paralleled by a significant between group reduction (improvement) in upper arm tissue density and a significant within group reduction in chest tissue density, both on the affected side. After the yoga intervention ceased, however, from 8b-12 the intervention group recorded a significant within and between group **increase** in the affected arm volume of lymphoedema, even though it continued to show a significant within group **reduction** in affected upper arm tissue density. There was no change in scores for chest tissue density. The abovementioned one-month long *tai-chi* intervention (Moseley, et al., 2005) reported significant within and between group reduction in chest tissue density combined with a trend towards reduction in percentage of arm volume of lymphoedema ($p=0.07$). This would seem to indicate that, if lymphangiogenesis occurred in the current trial, it was primarily related to the reduction in tissue density in the chest rather than in the upper arm. In the interview, four women (27%) associated a softening of the chest or shoulder area with a reduction in lymphoedema. As there is a lack of other studies reporting tissue density outcomes, no firm conclusion can be made at this stage, other than the need for further research.

There is also speculation that, if the flexibility of the chest improves in those with fibrosis from lymphoedema, certain shoulder ROM and strength movements may also improve (Jahr, et al., 2008; Johansson, et al., 2001; Lee, et al., 2007). From b-8, the significant within group improvement in tissue density for the affected upper arm and affected chest recorded by the intervention group was paralleled by significant within group improvements in shoulder ROM in internal rotation for the affected arm and strength in abduction for both arms over the same time period. These improvements did not occur in the control group. Impaired shoulder ROM in internal rotation has been connected with the presence of fibrous tissue (Johansson, et al., 2001). As the strength action of abduction requires the chest to open to

place the humerus in the subacromial space, it is highly probably that this action was improved by the lower tissue density. Three women (20%) reported in their interviews an association between reduced tightness in their chest or shoulder and increased shoulder mobility.

From 8b-12, there was no change in chest tissue density in the intervention group. However, tissue density reduced significantly for the upper arm on both sides. The intervention group also recorded a significant within and between group **decrease** in shoulder ROM in internal rotation for the affected arm, and a **decrease** in abduction for both arms. These decreases were paralleled by significant within and between group **increases** in arm volume of lymphoedema. This may indicate that it was an improvement in chest tissue density rather than in upper arm tissue density that had enabled the improvements in these movements from b-8. A further explanation could be that ROM and strength for women with BCRL are affected by both tissue density and lymphoedema levels. Another study based on gentle exercise resulted in a significant between group improvement in internal rotation for the affected arm, and trends towards improved lymphoedema levels recorded by volume and L-dex, but it did not measure tissue density (McClure, et al., 2010), while the aforementioned *tai-chi* study did not measure shoulder ROM (Moseley, et al., 2005), and as a result, no firm conclusion can be made. Nonetheless, it would appear that the yoga intervention had an effect in improving shoulder movement by reducing tissue density and perhaps volume of lymphoedema.

In addition to the reductions in tissue density in the upper arm and chest, the intervention group improved significantly, in comparison to the control group, in symptoms as a sub-scale of QOL at week 8. This supports the similar findings of the abovementioned *tai-chi* trial which reported significant within and between group decreases in perceptions of arm heaviness and limb size, along with significant within and between group reduction in chest tissue density (Moseley, et al., 2005).

Others have proposed that restoring correct movement patterns can reduce fibrosis and its associated pain, as well as the level of lymphoedema (Schrale & Ryan, 2011). It was hoped that the yoga used in the current trial would improve movement patterns; in other words, the emphasis was not so much on increasing the ROM and strength of the spine and shoulder area as on improving how the body moved, by focussing on the correct usage of the kinematic chain, core and shoulder stability and symmetry between sides. The results showed that, from b-8, the intervention group achieved symmetry between sides in ROM and strength of the shoulder as well as a significant between group improvement in pelvic stability in lateral flexion of the spine. This improved movement pattern may have contributed to the significant between group improvement in the intervention group at week 8 in affected upper arm tissue density, as well as to the significant within group reductions in chest tissue

density and arm volume of lymphoedema. However, no definite conclusion can be made, as at week 12, some of this improved movement was lost in the intervention group, while the fibrous tissue continued to decrease in the upper arm, forearm and upper back.

In summary, from b-8, there was significant between group reduction in tissue density for the affected upper arm and a significant within group reduction for the affected chest, in the intervention group. Reductions in shoulder and chest tightness were also reported in the interviews. These improvements may be attributed to the actual movement of the upper body, combined with breathing, which was emphasised in the yoga intervention. It appeared that reduction in tissue density, particularly in the chest, was associated with reduced levels of arm volume of lymphoedema and symptoms, and with improved ROM in internal rotation for the affected arm and abduction strength in both arms. Whether these improvements indicate that lymphangiogenesis occurred is unclear, since they were not sustained at the week 12 measurement. Also, lymphangiogenesis was not measured. Although no firm conclusions can be made, these findings add to those of the *tai-chi* trial (Moseley, et al., 2005) and point to the need for further investigation. Nonetheless, yoga did have an effect in reducing tissue density to week 8 and this improvement continued, except in the chest, to week 12, irrespective of other changes.

6.4.3 Level of sensations, pain, fatigue and degree to which they limited daily activity

The VAS scale for the current trial was specifically aimed at the three domains of sensations, pain and fatigue, to ascertain whether the yoga had any effect in decreasing their magnitude and lessening the limitations they may cause to women's daily activity.

Sensations had high scores on the VAS scale in both groups and were also commonly reported in the baseline questionnaires and interviews. The most common sensations reported were heaviness, tingling, tightness, numbness and aching. These results concur with those previously reported (Armer, et al., 2003; Edwards, 2000; Langbecker, Hayes, Newman, & Janda, 2008; Radina, et al., 2007; Ridner, et al., 2011; Sagen, Karesen, Sandvik, et al., 2009; Stout Gergich, et al., 2008). Heaviness was the most frequently reported sensation. Some women in the current trial also reported warmth and heat as sensations they associated with lymphoedema; however, these sensations have been reported less often (Moseley & Piller, 2008; Thomas-MacLean, et al., 2005). Heaviness and numbness decreased in the yoga participants' self-report of sensations at each measurement, and in the interviews eight women (53%) spoke about a reduction in heaviness. The VAS scale recorded an increase at week 4 and decrease at week 8 in the intervention group. Although not significant, this decrease paralleled the significant between group reduction in the QOL sub-scale of symptoms reported and discussed in the next section.

As in other studies (Dawes, et al., 2008; Edwards, 2000; Sagen, Karesen, Sandvik, et al., 2009), pain was highly reported in the current trial by 15/23 participants in the baseline

questionnaires. The effect of the yoga intervention was not clear. In the interviews, five women made 11 comments about pain reduction from the yoga, while five said they had felt no pain during the period of the intervention. The VAS scale showed a trend of increasing at week 4, decreasing at week 8, and increasing again at week 12. In the literature, pain reduction from a yoga intervention is also unclear. A review of randomised and non-randomised controlled trials that investigated the effect of yoga on pain from various causes found a positive outcome, though it recommended larger trials be undertaken before conclusions about yoga and pain could be made (Bussing, et al., 2012). In relation to yoga and breast cancer, an RCT, using a scale of 0-9 to signify levels of pain, reported that the yoga group, compared to the control group, had significantly greater improvements after eight weeks of yoga and at the 12-week follow-up (Carson, et al., 2009). However, a 12-week yoga and breast cancer trial measuring pain as part of its QOL tool found a significant increase in the pain level of the yoga group in comparison to the control group (Culos-Reed, et al., 2006). The researchers surmised that this may have been due to an increase in body awareness experienced by the yoga group.

Fatigue had higher VAS scores than pain at all time-points. This is similar to the high report of fatigue in women with BCRL in another study (Armer & Porock, 2002). Again, the effect of yoga intervention on fatigue was not clear. Subjectively, only one woman mentioned reduced fatigue and two reported higher energy in their interviews. However, an improvement in sleep was reported by nine women with 11 comments. Improvement in sleep is commonly reported after a yoga intervention with ill populations (Bower, et al., 2005; Garrett, Immink, & Hillier, 2011; Smith & Pukall, 2009). Sleep has been reported as a problem for women with BCRL (Ridner, et al., 2012) and may be an indicator of the level of fatigue. The VAS scale resulted in an improvement trend in fatigue only at week 8, which is different from a number of yoga studies that have reported a statistically significant improvement in fatigue for women during their breast cancer treatment (Bower, et al., 2011; Danhauer, et al., 2009; Danhauer, et al., 2008; Vadiraja, Rao, et al., 2009). The fatigue caused by lymphoedema may therefore be different from that caused by breast cancer treatment. Sleep may have been a more precise measure.

Women were also asked to record to what extent sensations, pain and fatigue limited their daily activity. There was a significant between group result at week 4 for the degree to which pain limiting activity occurred, due to the significant increase in the control group and the decrease in the intervention group. At week 4, the level of pain in each group was similar; in fact, it had increased slightly in the intervention group and decreased significantly in the control group, and yet the amount of pain experienced limited the activity of the control group significantly. This may be a result of the mindfulness practices of yoga, which encourage witnessing the pain rather than reacting to it, and allow physical activity to be performed, irrespective of the pain level. Another yoga study found a positive correlation

between women finding benefit from breast cancer and the high number of negative, intrusive thoughts. Such an unusual correlation was attributed to the witnessing aspect of the mindfulness practices of yoga, so that although the participants still had negative thoughts, they did not react to those thoughts (Chandwani, et al., 2010). The above results indicate that yoga may have a positive effect in reducing the limiting effect of pain from lymphoedema on daily activity. This is an important result and is in concordance with the recommendation that pain treatment, as well as CLT, needs to be included in the treatment for women with BCRL to improve their physical functioning (Dawes, et al., 2008).

In trials of upper body impairment from breast cancer, including lymphoedema, VAS scores of >20 mm for pain and sensations have been reported as affecting daily living (Sagen, Karesen, & Risberg, 2009), and more specifically, pain measured at 27 mm caused problems in reaching overhead and sleeping (Karki, et al., 2005). The mean VAS scores in the current trial reported >20 mm for sensations, fatigue and pain at different time-points. At week 4, the intervention group recorded 29 mm for sensations, which was the only score that surpassed 27 mm and may explain the reason for the lower ROM and strength recorded by that group compared to the control group.

To sum up, at week 4, compared to baseline, pain limited the activity of the control group significantly more than it did the intervention group. Eight weeks of yoga were needed for levels of sensations, pain and fatigue to have a trend of reduction in the intervention group. This trend also led to lower levels at week 8 in the intervention group than in the control group. However, as with lymphoedema levels, they began to increase again from 8b-12, which may indicate trials of longer duration are warranted to create significant results or to sustain the improvement.

6.4.4 Quality of Life

At baseline, the scores for total QOL in the control group were higher than those in the intervention group. In comparison to the control group which maintained its level, there was a gradual improvement in total QOL in the intervention group from b-8. Although not significant, this improvement was sustained until week 12, when the intervention group score became higher than that of the control group. Though many positive results exist from yoga interventions tested by RCTs **during** breast cancer treatment (Chandwani, et al., 2010; Rao, et al., 2009; Rao, et al., 2008), only two RCTs examined the effect of yoga on global QOL **after** breast cancer treatment, with varying results. The first consisted of a seven-week yoga intervention, which resulted in a significant improvement in global QOL that was not maintained at the three month follow-up (Culos-Reed, et al., 2006). The second resulted in a non-significant improvement after 12 weeks of yoga intervention (Moadel, et al., 2007).

In the current trial, group means for QOL were high in both groups at all time-points (range 6.8 – 7.9). These scores were surprising given the emotional experiences many of the

women were facing at this time due to their own severe illness or the death or illness of their spouse. Women reported in their demographic questionnaires that they "just had to get on with it" and it appears as if this is what they did. This attitude is the opposite of responses in other studies of women's self-report on the effect of lymphoedema on their lives (Armer & Whitman, 2002; Ridner, et al., 2012; Thomas-MacLean, et al., 2005).

The high total QOL scores in the current trial are different from those reported in other research (Beaulac, et al., 2002; Pyszel, et al., 2006) but similar to the conclusion of a systematic review that reported on the results of several studies which used similar QOL questionnaires to that of the current trial, with scores based on a scale between 1 and 10 (Lee, et al., 2008). The researchers found QOL was generally high amongst women after treatment which included surgery, axillary dissection and radiation (34% of women had lymphoedema) and surmised that it was as a result of the "ceiling effect" caused by having breast cancer, namely that all else is less important. Women in the reviewed trials rated their total QOL after breast cancer treatment between seven and eight, which was comparable, according to the researchers, to the score recorded by healthy, age-related women. As the total QOL score by week 12 in the current trial was also between seven and eight in both groups, it would appear that the women had a fairly high QOL, irrespective of their lymphoedema status. However, the interviews revealed a high level of anxiety about breast cancer, from its initial diagnosis through to the fear of its possible recurrence, in each of the 15 women. This may indicate that it is impossible to study BCRL as a condition totally independent of breast cancer, a suggestion also made by other researchers (Johansson, et al., 2003, p. 40). In future research, it may be preferable to use a QOL questionnaire that includes a section referring to breast cancer. The LYMQOL questionnaire, specific for lymphoedema, did not include a section on the effect of breast cancer.

A significant between group result in the sub-scale of symptoms occurred from b-8 in favour of the intervention group, due to the increase in the control group and the decrease in the intervention group. Reductions in symptoms have been recorded in studies reporting the effect of yoga therapy as part of a holistic treatment for lower limb lymphoedema (Narahari, et al., 2007) and in RCTs with resistance (Schmitz, Ahmed, et al., 2009) and *tai-chi* interventions (Moseley, et al., 2005). In the current trial, the women in the intervention group were able to maintain their improvement in symptoms from 8b-12. From 8b-12, the control group experienced a significant improvement in symptoms, possibly partly due to the significant reduction in fibrous tissue in the affected upper arm and upper back and non-affected forearm and upper arm. If this was indeed the case, the continued reduction in fibrosis experienced by the intervention group may also help to explain its sustained improvement in symptoms.

In the other sub-scales of function, appearance and emotions, the intervention group's means improved from b-8 however there was no significant change compared to the control group. Other RCTs for BCRL have resulted in significant improvements in function and appearance in the intervention group in comparison to the control group. A trial based on a gentle intervention with relaxation led to an improvement in function at the three-month measurement (McClure, et al., 2010). In the PAL resistance training trial, there was an improvement in body image at the 12-month measurement (Speck, et al., 2010). The results from yoga RCTs on women after breast cancer treatment are less clear. One trial reported no significant improvements on functional, emotional or physical sub-scales after a 10-week yoga intervention (Danhauer, et al., 2009). In contrast, a 12-week yoga intervention resulted in significant improvements on the emotional sub-scale and total QOL in the intervention group compared to the control group (Moadel, et al., 2007). Perhaps the improvements mentioned are related to the longer intervention in the above trials and indicate that a longer intervention in the current trial was needed to create significant changes in these sub-scales.

The lack of change that occurred in these sub-scales in the current trial may also have been due to the low levels reported. For example, in their baseline information, women reported a low level of embarrassment about their appearance, which is different from other studies (Johansson, et al., 2003; Koelmeyer, et al., 2010; Ridner, 2005; Ridner, et al., 2011). This lack of embarrassment extended to the wearing of a compression sleeve, perhaps due to the cold climate in Tasmania, which makes wearing it more comfortable and hiding it under clothing easier. This is in contrast to women who live in tropical Australia (Gordon, Sheppard, & Selby, 2009).

However, there were considerable individual variations in the different sub-scales and total QOL scores. (An example of one participant's radical improvement in total QOL and the sub-scales was provided in Chapter 4, Results 2, *Figure 4.17*). This may indicate that this group of women is generally able to cope well with lymphoedema and only needs support in the areas that affect them. This idea is supported by the findings of a recent Australian study (Girgis, et al., 2011). Alternatively, it may indicate that current education about lymphoedema and appropriate treatment is more effective than in the past, as has been suggested in another Australian study (Sherman & Koelmeyer, 2011).

From 8b-12, however, the sub-scale of function decreased significantly in the intervention group, parallel to the significant increase in arm volume of lymphoedema and the significant reduction in ROM in internal rotation for the affected arm and loss of symmetry in ROM. This may suggest an association between the level of lymphoedema, shoulder ROM and function, since the improvements from b-8 were not sustained after the intervention ceased. A similar association between these domains is reported in the literature (Hayes,

Battistutta, Parker, et al., 2005; Hayes, et al., 2008b; Pyszel, et al., 2006), and was more noticeable at the week 12 measurement than at baseline.

The interviews highlighted other specific aspects of QOL that the LYMQOL questionnaire did not examine, once again attesting to the need for a variety of measures (Hayes, Battistutta, & Newman, 2005). Positive remarks with high frequency were made about improved equanimity and calmness, wellbeing, increased time for self and self-effectiveness, better relationships and heightened mental awareness. These are important aspects of QOL for women with BCRL. The enjoyment of the group dynamic mentioned in the interviews by all 15 women has also been reported in many other exercise trials for women with BCRL (Hayes, Speck, Reimet, Stark, & Schmitz, 2011; McClure, et al., 2010; Tidhar & Katz-Leurer, 2010) and in yoga trials (Galantino, et al., 2011; Ulger & Yagli, 2010). Further, the very real emotive concern about the effects from their breast cancer experience was reported by all the women who were interviewed. This concern, which was also voiced by women in other trials (Johansson, et al.; Norman, et al., 2009; Ridner, et al., 2012), would not have been picked up if only the LYMQOL tool had been used.

In summary, at week 8, the QOL sub-scale of symptoms improved significantly in the intervention group compared to the control group. Total QOL scores were high for both groups, but whereas the score remained even for the control group, it continued to improve for the intervention group. The interviews revealed subjective improvements that may have not been otherwise picked up, including the continued emotive concern derived from having a diagnosis of breast cancer. From 8b-12, the total QOL score became higher for the intervention group, and while other sub-scales were relatively unchanged, function increased (worsened) significantly in the intervention group and symptoms decreased (improved) significantly in the control group. A longer intervention may have produced additional significant results.

6.5 Secondary outcomes

The effect of the yoga intervention on upper body function was assessed by evaluating the ROM of the shoulder and thoracic spine, grip strength and the strength of the shoulder and the three separate muscles affected by treatment (serratus anterior and pectoralis major and minor).

6.5.1 Range of motion of the shoulder

Shoulder ROM increased significantly in the control group, compared to the intervention group, in flexion and abduction for the non-affected arm. These results were due to the increase in the non-affected arm in the control group compared to the decrease in the intervention group. However, as a result of this decrease, combined with the increased ROM for the affected arm, which was significant for flexion, ROM became similar for both arms in the intervention group (represented graphically in Chapter 4, Results 1, *Figure 4.10*). This

pattern was repeated for the other ROM scores in the intervention group, except in extension, and meant that a more symmetrical movement pattern occurred. Loss of symmetry between sides can be an outcome of BCRL (Rostkowska, et al., 2006) and can affect everyday functioning (Balzarini, et al., 2006). Restoring symmetry between sides is beneficial for women with BCRL and has been recommended as an important focus in rehabilitation (Balzarini, et al., 2006; Hayes, et al., 2012). It is also an aim of yoga (Coulter, 2001). This is, therefore, an important outcome. That this pattern of increased symmetry is attributable to the yoga intervention is highly probable, as it was not maintained from 8b-12, when the shoulder ROM scores began to separate again in the intervention group, except in flexion.

In addition, there were a number of significant within group improvements in both groups. The increase in ROM in so many of the control group scores at week 8 may be due to the larger amount of physical activity recorded in the IPAQ questionnaires, and the higher attendance at organised exercise classes. Other researchers have reported improved arm function as a result of increased physical activity (Pain, Vowler, & Purushotham, 2003; Sagen, Karesen, & Risberg, 2009). The intervention group had significant increases in ROM for the affected arm in flexion and internal rotation, and for both arms in extension.

Shoulder ROM actions can be affected by the tightness at the chest that can occur after breast cancer treatment (Yang, et al., 2010) and from fibrosis from lymphoedema (Armer, et al., 2003; Girgis, et al., 2011; Morgan, et al., 2005). If left untreated, chest tightness can lead to a permanent reduction in these actions (Johansson, et al., 2001). Shoulder ROM and chest mobility are dependent on thoracic spine mobility, which is also affected by breast cancer treatment (Crosbie, et al., 2010; Crosbie, et al., 2008). A gentle daily 17-minute exercise and relaxation intervention for women with BCRL produced a significant between group improvement in internal rotation and summated shoulder ROM of the affected arm (McClure, et al., 2010). It is possible that exercise based on the actions that combine thoracic and shoulder ROM, along with the slow breathing that occurs in yoga, may be an effective way to restore mobility to the chest. Such actions may also lead to the kind of reduction in tissue density reported in the primary outcomes, and this may, in turn, increase shoulder mobility. As one participant put it: "My arm and chest are not as tight…I now have better movement in both sides of my chest….and I have been able to return to swimming."

To sum up, the intervention group achieved symmetry between arms in ROM actions from b-8. This was different from the increased ROM for both arms in the control group (perhaps due to the return to exercise classes by members of the control group). This symmetry in the intervention group was not maintained to week 12.

6.5.2 Grip strength

The significant between group result from 8b-12 in favour of the intervention group for grip strength was due to a significant decrease in the control group. There was no apparent

reason for this result, although it may have been linked to the greater amount of physical activity being undertaken by the control group and to the affected arm being fatigued.

Apart from this unexplained decrease in the control group at week 12, scores for both groups changed very little, a feature noted in other trials reporting on lymphoedema and grip strength (Beaulac, et al., 2002; Dawes, et al., 2008). It would appear, therefore, that women with BCRL may not have impaired grip strength. Indeed, when compared to grip strength age-related norms (Bohannon, Peolsson, Massy-Westropp, Desrosiers, & Bear-Lehman, 2006), the results for both groups in the current trial fitted into the lower end of normal range, indicating that grip strength was not a major problem for them.

This result is in contrast to the difficulties that have been previously reported by women in actions requiring grip strength, such as repetitive hand actions, carrying, holding something and fine motor skills (Norman, et al., 2009; Thomas-MacLean, et al., 2005). Many of these difficulties were also reported in the baseline questionnaires in the current trial. Hand dexterity and coordination, rather than grip strength, were tested in a cross-sectional trial that investigated the impact of lymphoedema on arm and hand function (n=50). These tests also produced no change (Dawes, et al., 2008). The researchers concluded that pain, rather than dexterity, reduced hand function. This association was not tested in the current trial.

An improved measure may be to include functional questions about hand usage and what causes limitation in future trials for women with BCRL. Nonetheless, there did seem to be a link between changes in grip strength and hand volume of lymphoedema, at the group and individual level (as reported in Chapter 4, Results 1), so further investigation of that link may be warranted.

6.5.3 Strength of the shoulder

Although there were no significant between group results in shoulder strength, each group had significant within group results. The control group had significant improvements in flexion and horizontal adduction for the non-affected arm at week 4, and maintained the score to weeks 8/8b and 12. This may have resulted from the large amount of group exercise, gym work and supervised exercise training being undertaken by the control group.

The intervention group had a sustained significant improvement in abduction for both arms at weeks 4 and 8. Similar improvements have been reported in two other eight-week RCTs on women after breast cancer treatment (Kilbreath, et al., 2012; Lee, Kang, et al., 2010). The first trial compared a group which received combined progressive strengthening and passive stretching with a focus on the shoulder, with a group told to continue to use the arm, and resulted in a significant between group improvement in abduction for the intervention group (Kilbreath, et al., 2012). The second trial compared general exercise with scapulothoracic stabilising exercises in women after breast cancer treatment and resulted in

a strong trend for improved abduction (p=0.07)in the group focussing on shoulder stabilisation (Lee, Kang, et al., 2010).

Both of the abovementioned trials focussed on resistance training, along with shoulder stabilisation. The current yoga trial focussed on shoulder stabilisation during ROM actions. There was no weight-bearing on the arms. However, muscles were tensed on the pause after the inhalation, while maintaining stability of the joints, in order to create pressure changes to enable the lymph to flow. It may be this action, along with the activation of the stabilising muscles of the scapulohumeral joint that led to the improved strength in abduction.

A trial to test the activation of stabilising muscles, using electromyography, compared symptomatic and asymptomatic adults. Activation of scapula-stabilising muscles occurred in both groups when performing gentle but specific movements. The movements undertaken were similar to many of the yoga postures in the current trial. The researchers concluded that, in spite of shoulder impairment, certain movements can be used to strengthen stabilising muscles of the scapula and shoulder. Such activation leads to more space in the subacromial area, which improves shoulder functioning (Kibler, Sciascia, Uhl, Tambay, & Cunningham, 2008). Abduction requires contraction of the supraspinatus muscle and the deltoids, which can occur only when this subacromial space exists. Improved stabilisation, albeit through gentle yoga movements, may explain the significant improvement for both arms in abduction experienced by the intervention group at weeks 4 and 8. However, the improvement was not sustained from 8b-12, which could indicate that the intervention was not long enough to ensure the women continued to adopt shoulder stabilisation in their daily actions. Nonetheless, it may be that yoga can provide a gentle and rehabilitative return to strength in women with BCRL.

Functional difficulties that have been reported in women with BCRL, such as lowering a weight from overhead or pushing a vacuum cleaner (Norman, et al., 2009; Ridner, et al., 2012; Thomas-MacLean, et al., 2005), actions that involve extension and horizontal adduction respectively, were also reported by the women in the current trial in their baseline questionnaire. These actions did not improve in either group in this trial. However, two RCTs offering resistance training to women with BCRL over six and 12 months respectively resulted in significant increases in bench press strength (Ahmed, et al., 2006; Schmitz, Ahmed, et al., 2009). The bench press movement involves horizontal adduction using both arms simultaneously, so although a comparison between those results and the current trial cannot be made, it does show that with resistance training, these muscles can improve. In the interviews, women described many strategies for coping with these difficulties, such as using their non-affected arm, standing on foot stools, changing arms frequently, putting heavy items on lower shelves or asking their husband to perform the required action. It may be that

strengthening of the muscles required for these actions should be targetted in yoga for women with BCRL.

To sum up, the significant within group improvement in abduction for both arms in the intervention group at week 8 may indicate improved stability of the shoulder; however, this was not sustained from 8b-12. Although there were significant within group improvements in the control group for the non-affected arm at week 4, neither group improved in horizontal adduction or extension for the affected arm throughout the trial, which may indicate a need to target these actions in future yoga trials.

6.5.4 Strength of serratus anterior, pectoralis major and pectoralis minor

It was predicted that the gentle movements of yoga, focussing on stability and correct kinematic movement, would result in improved function of the pectoral and serratus anterior muscles. Overall, however, the scores and significant results were similar in each group (reported in Chapter 4, Results 1, *Figure 4.11*). The exception was the significant between group result from 8b-12 for the non-affected pectoralis major, due to the significant decrease in the intervention group. There is no apparent reason for this.

The similar scores may be an indication of improved measuring instruction as the trial continued and of the women in both groups better understanding how to isolate these muscles for the measurements. However, the similar results may also be due to the actual similarity in weakness in these muscles within the group as a whole. This weakness is reported in women after breast cancer treatment, in particular after mastectomy and axillary dissection (Shamley, et al., 2009; Shamley, et al., 2007), and in women with BCRL (Balzarini, et al.; Johansson, et al., 2001). In fact, it has been suggested that, if these muscles are not retrained early, they may not be able to return to pre-surgery functioning (Johansson, et al., 2001).

Strength may be an inappropriate measure of these muscles. Perhaps measuring changes in **how** these muscles are activated pre- and post-intervention would provide more helpful information. Electromyography, electromagnetic imaging (Polhemus Fastrak™) and MRI (Kibler, et al., 2008; Lin, Lim, & Yang, 2006; Rundquist, 2007; Shamley, et al., 2009; Shamley, et al., 2007) have been used to provide such information, as well as show how the scapula moves after breast cancer treatment. One of these techniques may be more effective in future trials in detecting if the muscles have changed in how they function after the intervention.

6.5.5 Abdominal strength and posture

Posture and core strength were not measured in the current trial. Both were reported (non-prompted) in the interviews as having improved. Better posture was reported by eight

women and another six reported on core, abdominal or overall strength. These improvements concur with other yoga studies (Omkar, et al., 2009; Posadzki & Parekh, 2009).

As reported in Chapter 5, Results 2, all 15 members of the intervention group mentioned the fact that at the end of the study they were more aware of how their body moved, which is a distinctive focus of yoga (Evans, et al., 2009). It was this new-found physical awareness that women reported as having led to their improved posture. Physical awareness is also emphasised in rehabilitation after injury or impairment in order to reteach kinematic movement associated with the spine, scapula and shoulder. Two researchers have proposed that, given this focus, yoga could be offered in remedial physiotherapy (Posadzki & Parekh, 2009).

Further, there is a strong focus on core stability in yoga. Contraction of the core stabilisers of the pelvis, the transversus abdominis and pelvic floor muscles occurs in every yoga movement to varying degrees (Borg-Olivier & Machliss, 2004; Omkar, et al., 2009). Yoga breathing also engages core muscles and at times all the abdominal muscles (Petrofsky, et al., 2005). Throughout the yoga classes, physical practices were given that required strong abdominal contraction on the exhalation to empty the lymph back into the venous system at the lymphatic ducts so that lymph did not build up. This is an important aspect of lymphatic clearing and a practice that has been incorporated into the techniques used in Kerala, India for yoga therapy on lower limb lymphoedema (Narahari, et al., 2011).

There is, therefore, a possible explanation of how yoga could potentially lead to improvements in posture and core strength, and could perhaps be recommended as another form of early physical therapy for women with BCRL.

As there is a general lack of information about posture in women with BCRL - in fact, the principal researcher could find only one such study (Balzarini, et al., 2006) - there is also a need for posture in women with BCRL to be evaluated in future trials.

6.6 Spinal mobility

Compared to the control group, the intervention group had significantly more movement in the pelvis (pelvic obliquity) in lateral flexion at baseline. At week 8, there was a significant between group result due to the significant **reduction** in pelvic obliquity in the intervention group, compared to no change in the control group. Both groups were equal at week 12. The improvement may have resulted from the focus on core stability during the yoga intervention, as discussed in the previous section. An intervention based on core stability has previously been reported to significantly reduce pelvic obliquity in a group of 17 healthy young adults (Kaji, Sasagawa, Kubo, & Kanehisa, 2010) which the authors attributed to improved core stability and posture. In the current trial, core stability was taught but not measured, however eight participants (53%) reported on improved posture in the interviews.

Increased physical awareness was reported by 15 women (100%) which probably also improved women's posture and way of moving. Women attributed these improvements to the yoga intervention discussed in the previous section (6.5.5).

It was anticipated that the yoga intervention may lead to increased spinal mobility, as had occurred with a week-long intensive yoga intervention on people with lower back pain (Tekur, et al., 2008). Increased spinal mobility increases the movement of tissue at the chest and upper back, which has been hypothesised as a possible means of reducing the fibrous tissue associated with BCRL (Moseley, et al., 2005). Thoracic spinal mobility is also connected to the mobility of the shoulder and scapula (Crosbie, et al., 2008), and so it was predicted that it would also help with the upper body impairment associated with BCRL.

In fact, there were no further significant between group changes. This may have been because the intervention was too short. For example, in the current trial, a non-significant between group difference occurred in the angle of kyphosis at rest, due to the increase in the control group and decrease in the intervention group at week 8 ($p=0.070$). This is a similar result to a pilot 12-week non-randomised yoga study with one session per week for people with hyperkyphosis, where participants reported improved posture but no significant improvement in angle of kyphosis (Greendale, et al., 2002). However, an RCT with yoga intervention over a longer duration, three one-hour sessions of yoga per week over 24 weeks, reported a significant reduction in the angle of kyphosis in people with hyperkyphosis, compared to the control group (Greendale, et al., 2009).

Further, flexion/extension of the thoracic spine is the action associated with the arm action that reduced fibrosis of the chest in a *tai-chi* trial (Moseley, et al., 2005). As in that trial, intervention participants in the current trial had a significant reduction in chest tissue, but this was not matched by a significant improvement in the thoracic range of flexion/extension. Perhaps again due to the inadequate duration of the intervention as there was evidence of individual change. One participant stated in her interview: "I'm convinced that the yoga is improving my shoulders and thoracic spine and the lymph drainage" (L01), and also reported improved flexion of the shoulder, which requires extension of the thoracic spine. These observations were supported by her objective scores, for flexion of the shoulder, thoracic range in flexion/extension as shown graphically in Chapter 4, Results 1, *Figure 4.15* and reduction in chest tonometry at week 8. Similar results also occurred for three other participants in the intervention group (H17; L08; L011) who took part in the spinal mobility tests.

Both groups significantly decreased in full range of lateral flexion from b-8 which appeared to be related to non-significant changes in **how** each group moved. Both groups reduced the degree of lumbar range and increased the thoracic range, closer to the desired ratio of 1:3 (Sahrmann, 2002). This improved movement pattern in lateral flexion may have

been a result of a better understanding of the assessors' instructions. Although not significant, each group increased their thoracic range in a different area. The intervention group increased in the lower thoracic spine, which is the optimal movement pattern (Edmondston & Singer, 1997; Sahrmann, 2002), and the control group in the upper thoracic spine. Perhaps longer time was required for this difference to become significant.

During the interviews, six women made 11 comments about feeling more supple and moving with greater ease and flexibility, and these changes were supported by their objective spinal results, as exemplified in Chapter 4, Results 1. However, it was surprising, given the focus on spinal mobility that is a feature of yoga practices, that there were not more significant improvements in the intervention group compared to the control group. This may support the finding of another study on women with BCRL that thoracic spinal problems were not present (Balzarini, et al., 2006). It may be too that the intervention was not long enough to produce significant between group results. Another consideration could be the low sample size.

In comparison to norms for spinal mobility (White & Panjabi, 1978; White, Panjabi, & Thomas, 1977), women in the current trial were lower in flexion/extension and lateral flexion and within the normal range for rotation. In comparison to women who were healthy, obese or obese with lower back pain (Menegoni, et al., 2008; Vismara, et al., 2010), using the same measuring method, the women in the current trial had greater pelvic obliquity, a higher angle of kyphosis and reduced lateral flexion. The yoga intervention showed improvement in pelvic obliquity, along with a trend to improved angle of kyphosis. Given the current lack of research in this area, it would appear that further investigation into the spinal mobility of women with BCRL is warranted.

6.7 The yoga class and DVD

As this was the first eight-week trial of yoga on women with BCRL, the aim of the interviews was to obtain subjective feedback on the effect of the yoga intervention. This feedback has been included in the above discussion of the primary and secondary outcomes. In addition, the women were asked to comment on the effectiveness of the yoga class and DVD and, in particular, to suggest what could be improved. Satisfaction with the yoga intervention was prominent in the interviews. The length, lack of rush before and after the class, modification and progression of postures were particularly appreciated and may have influenced the high attendance and compliance rate to the class and DVD. These factors are worth considering for future trials, as other yoga trials for women with breast cancer have reported low compliance (Chandwani, et al., 2010; Moadel, et al., 2007).

These factors may have also influenced the positivity expressed by each woman to the group dynamic that occurred. Support from a group is beneficial to women with BCRL (Greenslade & House, 2006; Ridner, 2009), and so practices that will promote this are

important. Surprisingly no-one spoke about increased spirituality which women with BCRL have reported as helping their QOL (Ridner, et al., 2012), in spite of time being allocated in each lesson to discussion of the philosophy of yoga. As increased spirituality has been reported in other yoga trials (Danhauer, et al., 2009; Moadel, et al., 2007). The lack of comment in the current trial may be a result of six of the intervention women saying they approached yoga with great scepticism, and their previous lack of experience with yoga. Perhaps longer exposure to yoga is necessary to gain spiritual awareness.

The women reported benefit from each aspect of the yoga intervention. They were surprised at how gentle the yoga postures seemed to be and enjoyed the postures becoming progressively more difficult. Thus, yoga may provide an intermediary to stronger exercise and counteract the fear that some women have in returning to stronger exercise (Hayes, Reul-Hirche, et al., 2009; Lee, et al., 2009). The women further reported using the relaxation when they needed to de-stress or go to sleep, and the benefit of slow breathing to calm themselves. Improved QOL is a vital aspect of lymphoedema management and it would appear that an integrated system of yoga practices, as provided in the current trial, may help to improve the biopsychosocial needs of women with BCRL.

As the women commented favourably on all aspects of the DVD, it would appear that its current format could be used in future trials and for women with BCRL in a home-setting. In this way it may provide variety and interest to the daily self-management required by women with BCRL.

6.8 Limitations and strengths of the current trial

6.8.1 Limitations

The sample size for statistical analysis was small, and so further trials are necessary to substantiate the findings. The length of the trial was eight weeks and may not have been long enough to obtain more substantial results. Also the duration of the yoga classes was 90 minutes, and the home-practice DVD was 45 minutes, shorter or longer sessions may have yielded different results. The demographic and medical information was based on self-report rather than on medical records, and so it may contain errors.

The yoga intervention of the current trial was based on Satyananda Yoga™ specifically developed for women with BCRL based on lymphatic clearing. Its outcomes may not be transferrable to other styles or methods of yoga.

As there was no BIS equipment in Tasmania before the hiring of this equipment for the current trial, L-dex levels were unavailable pre-trial. Likewise, lymphoedema therapists reported that they went by "feel" and circumferential measurements rather than by calculating volume levels, so lymphoedema volume levels were also unavailable pre-trial. As funds were limited, these measurements could not be carried out prior to baseline. As a result,

levels of lymphoedema by L-dex and arm volume were lower than expected. However, all women had been clinically diagnosed with lymphoedema.

The timing of the trial was chosen for the end of summer (late February) to enable the women to attend measurements and yoga classes while it was still light, and before winter set in, when weather conditions can become adverse in Tasmania and it gets dark very early. Many Tasmanians also go away in the winter months. However, late February to early March is also the time that many exercise classes resume after the Christmas break in Tasmania, which meant that many women in the control group returned to their physical activity classes, and in fact, throughout the trial took part in more physical activity than the intervention group. This increased activity by the control group may have affected their results.

The hand-held dynamometer, as a measure of shoulder strength, was a difficult instrument initially. Although the assessors had been trained and had practised on a small number of women with BCRL, they felt that they gave better instructions, and that both they and the participants better applied their resistive force, at week 4 than at baseline. As this trial was limited in funding and there was no fixed position dynamometer easily available in Hobart, it was decided to use the hand-held instrument. In future trials, a larger practice run may reduce the problems or a fixed position dynamometer, if available, may be more reliable.

Further, instead of testing the strength of the separate muscles, an improved measure may be to investigate the changes in how these muscles operate pre- and post-intervention. The optimum for this type of measure would be three-dimensional testing units, as used in other trials.

The measurement of spinal mobility depended on translucent markers attached to the skin, and although the utmost care was taken to ensure uniformity of placement, errors may have occurred. It was difficult to place the translucent markers in the lumbar region of obese women, and an extra rod had to be added in order to view the marker. As it was decided this may impact on results, not all scores for the action of flexion/extension were analysed.

The yoga lesson and DVD were formulated and taught by the principal investigator as she was qualified, accredited and experienced in both yoga therapy and MLD. Nevertheless she did not perform the outcome measures, and as information was coded for the statistical analysis, the data could not be identified and manipulated.

6.8.2 Strengths

The randomisation of the groups, the blinding of the assessors to group allocation and previous scores, and the use of established and validated measures are considered strengths

of the current trial, as well as the yoga intervention, which was based on researched principles and used a well-established yoga tradition.

The staffing and training of staff were further strengths. Two professional lymphoedema physiotherapists were used for lymphoedema measurements, one in Hobart and the other in Launceston. The same experienced and qualified interviewer conducted the interviews in Hobart and Launceston. The teaching of the yoga at both locations by the same highly experienced yoga teacher, who also had qualifications in CLT, ensured detail to any medical concerns that may have arisen, as well as consistency of the intervention. Trained fourth-year Human Life Sciences students conducted the other measures. In order to ensure accuracy, all staff had another person present to record the scores. Other staff being available at the measurement sessions meant the process flowed smoothly and any problems arising could be quickly solved.

Comprehensive processes were put in place for recruitment of women, group allocation, measurement protocol, reminders of measurement sessions, missed measurement sessions or yoga classes, data collection and storage.

As a result, motivation was high and maintained by both groups of women from baseline to week 12. This resulted in high attendance rates at the yoga classes and measurement sessions as well as high compliance with the DVD. In their interviews, women reported that this was a result of the excellent organisation, the friendliness and professionalism of all staff, the value of the group dynamic, the enjoyment of the yoga and the strong desire to help other women with lymphoedema. Women whose results had to be omitted as they no longer fitted the entry criteria, continued to attend the yoga and come to the measurements, such was their commitment.

Sound statistical analysis was conducted for demographics by SPSS software and for results of primary and secondary objectives by STATA software. The development of the themes and sub-themes by two researchers independently provided a good basis for qualitative analysis of the interviews.

As this was the first trial of an eight-week yoga intervention on women with BCRL, the multiple measures chosen gave a broad spectrum of outcomes. Any of these could be focussed on in future trials.

6.9 Conclusion

This discussion has contextualised the outcomes of the current trial within the field of BCRL in relation to existing and at times non-existent research in a cohort of Tasmanian women with similar characteristics to those of women with BCRL described in other studies.

The research adds to the growing field of research into physical therapies for women with BCRL. A major finding was that lymphoedema measured by BIS and volume was not exacerbated by yoga. Further, it adds to the evidence gained from a *tai-chi* trial that the gentle movement and slow breathing reduced tissue density and symptoms for the group receiving the intervention. The yoga intervention also reduced the effect of pain limiting daily activity perhaps due to the mindfulness component of yoga.

The eight weeks of yoga intervention also improved upper body function in various ways. In particular, shoulder ROM became symmetrical between arms, pelvic obliquity improved and the strength action in abduction for both arms improved. This was echoed in the interviews in which the participants spoke of improvements in posture, mobility, physical awareness and core stability and may indicate that yoga can provide a gentle return to exercise for women with BCRL. It may be the holistic aspect of yoga that could also reduce the fear many women with BCRL have in returning to exercise.

Further, associations were evident for which there is a paucity of research, such as an apparent association between the reductions in tissue density, lymphoedema volume and symptoms and the increased ROM action of internal rotation.

It was surprising that there were not more improvements in QOL and spinal mobility, but it may be that a longer intervention and a larger sample size was needed for this to occur.

The interviews gave further insight into the effects of yoga and the home-practice DVD that may not otherwise have been collected, specifically in terms of increased calmness and wellbeing, creating time for self and improved relationships. The relaxation was particularly enjoyed. Further, valuable information was collected about the yoga class and the effectiveness of the DVD that can inform future yoga trials. There was also a high level of association between subjective comments and objective scores, which is not usually reported in the literature. Perhaps this is another result of the mindfulness aspect of yoga, as women also reported improved physical and mental awareness in their interviews.

Although the trial had limitations, including the small sample size and the lack of pre-testing of lymphoedema levels, it also had many strengths, particularly the expertise of the assessors and yoga teacher, the protocols for the measurements and the yoga class and the statistical analysis. The current trial offers preliminary evidence that yoga may offer another self-management tool for women with BCRL and that further research is warranted.

CHAPTER SEVEN CONCLUSION

The aim of the current trial was to investigate the effect of yoga on women with BCRL. The primary objectives were to establish the effect of yoga on lymphoedema levels, tissue density, sensations, pain and fatigue and the degree to which sensations, pain and fatigue limited daily activity, and on QOL. The secondary objectives were to assess the effect of yoga on upper body function in terms of shoulder and spinal ROM and the strength of grip, shoulder and pectoral and serratus anterior muscles. The amount of physical activity being undertaken and medical and demographic information were also recorded. Further, women's subjective opinions were sought on the personal effects of yoga and the effectiveness of the home-practice DVD.

7.1 Summary of literature review

The literature review established that there was no published research into the effect of yoga on women with BCRL, but that a need existed since women were already attending yoga classes. It further provided information pertaining to the need for a holistic treatment of lymphoedema due to its physical, social and emotional effects and suggested that yoga, with its focus on body, mind and spirit, may fulfil these requirements. Research into the beneficial outcomes of exercise trials was examined, including options using *tai-chi* and breathing, gentle movements and relaxation, providing further support for a yoga intervention trial.

The physiology, effects and treatment of both breast cancer and BCRL were discussed to provide the necessary background information for the development of a safe and effective yoga program based on researched principles. Aspects of lymphoedema treatment and yoga practices that are similar, such as slow breathing, slow isotonic movements, rest periods and relaxation, were discussed, supporting the notion that yoga may be another self-management option for women with BCRL.

Although no yoga research exists for BCRL, other yoga research was discussed that may have transferrable outcomes, including yoga therapy as part of a holistic treatment plan for lymphoedema from filariasis, yoga therapy for breast cancer treatment and yoga for different conditions. The effect of specific yoga practices was also discussed.

7.2 Review of methods

7.2.1 Study design and protocol

All care was taken to provide a well-designed RCT, with assessors blinded to group allocation and previous scores and an effective protocol with trained staff, validated and established measures and detailed communication systems. Consistency of measurement

was achieved by the same staff member administering the same measure throughout the trial. The development of forms and processes for recruiting the women, recording the results and storing the data was also carefully planned and successfully carried out.

Steps to eliminate potential problems included:

A small pre-trial practice for assessors with women with BCRL to test the equipment, forms and flow of process;

Staff meetings at the end of the measurement sessions to discuss and resolve unforeseen problems;

The principal investigator and extra staff present at each measurement session to answer queries and solve problems;

A discussion at the beginning of each yoga class, to ensure participants were managing the intervention.

7.2.2 Measures

The medical information necessary to inform individual variation during the yoga intervention and measurements was collected at baseline. It also provided valuable background information about this cohort of Tasmanian women living with BCRL.

Differences in scores recorded by bioimpedance L-dex and arm volume of lymphoedema warranted the use of both measures. The measures of tonometry and VAS scales were effective.

LYMQOL had several deficiencies, which were commented on by women in both groups; for example, there was no question about the effects of driving or computer use on levels of lymphoedema. Further, it did not provide information about the continued stress women felt from their original breast cancer diagnosis; this was gained only from the interview. Another tool may provide more complete information.

Grip strength may be an extraneous measure that could be replaced by questions relating to what impairs hand actions. The exception would be a study that set out to compare hand volume of lymphoedema with grip strength, due to the apparent association found in the current trial between these measures.

A fixed dynamometer, rather than a hand-held dynamometer, for strength measures may be more reliable, if available.

The strength measure of the pectoral and serratus anterior muscles could be replaced by measuring how these muscles operate, by using three-dimensional equipment such as

myography or MRI. This may give more precise information about how an intervention affects these muscles.

The shoulder ROM measure was problem-free.

Due to visibility difficulties with the translucent markers on the skin of overweight participants in the spinal mobility tests, an improved method of optoelectronic equipment could be used.

The 20-minute duration of the interviews was appropriate, recording them on a digital instrument was effective, and the women did not appear inhibited in their desire to speak. The interviews were valuable for two reasons: firstly, they provided further information that was not gleaned from the objective measures and secondly, they showed a high level of association between comparable subjective and objective scores. As a result of this association, further insight was gained into the different benefits gained by different women, in spite of the uniformity of the intervention.

The use of many measures in the current trial gave an overview of the effect of yoga on women with BCRL. Future trials could focus on specific measures to further investigate the findings of this trial.

7.2.3 The yoga intervention

Attendance at the classes and compliance rates with the DVD were high. The yoga intervention had been developed over several years and was based on research in the fields of yoga, lymphoedema and yoga therapy for lower limb lymphoedema. A procedure was provided for missed classes. All participants found it easy to fill in the logbook to record their daily practice. This opportunity to document their responses to the home-practice was seen by all as an important and useful element in the process. Consistency and precision of teaching was provided at both locations by the same experienced and accredited yoga teacher, who also had qualifications in CLT.

7.2.4 Participants' satisfaction with process

There was a high satisfaction with the organisation of the trial and yoga classes reported by women at the measurement sessions and in the interviews for intervention participants.

7.3 Outcome of research questions

Outcomes of the study were:

1. For women with BCRL stage one, compared to the control group, the eight weeks of integrated yoga intervention:
    i. Did not exacerbate lymphoedema, lessened tissue density in the affected upper arm and reduced pain limiting activity;

ii. Reduced the QOL sub-scale of symptoms;

iii. Increased symmetrical movement patterns in shoulder ROM and improved pelvic stability in lateral flexion of the spine.

And in the intervention group, the integrated yoga intervention:

i. Reduced significantly the arm volume of lymphoedema and tissue density in the affected chest at week 8 and did not exacerbate sensations, pain or fatigue, with no change in the control group;

ii. Improved total QOL, while the control group maintained the baseline level;

iii. Increased significantly the shoulder ROM actions in flexion and internal rotation for the affected arm and the shoulder ROM action in extension and strength action in abduction for both arms. Improved in angle of kyphosis. In comparison, the control group improved significantly in several ROM actions for both arms and in flexion/extension of the spine.

And subjectively:

iv. Women reported enjoyment of and benefits from the class and the DVD. They particularly liked the relaxation, the individualised attention, modifications to practices and the progression of difficulty of the postures. Although some found some of the breathing practices took several weeks to master, including co-ordinating the breath with the postures, most also commented on the benefits. They felt that both the class and the DVD contributed to a positive increase in "time for self." Women also reported improvements in physical, mental and social areas of their lives. In particular, beneficial personal outcomes reported were increased physical and mental awareness and calmness, improved wellbeing, posture, flexibility, strength and physical function, and enjoyment of the group dynamic. These improvements led to nine women reporting a significant personal change that they felt happened as a result of their yoga participation. When comparable, subjective reports of individual improvements, made in the interviews, were supported by the objective results. All women were still highly affected by their breast cancer diagnosis.

2. Women enjoyed and gained benefit from the DVD. They reported that it was an effective mode of delivery for home-practice, easy to follow, of appropriate time-length and with clear instructions. They appreciated the modifications demonstrated in the DVD. Suggestions for improvement were related to the *yoga nidra* relaxation,

i.e. to have the visualisation the same in the DVD as in the class, and to slow it down a little. Further, most intended to continue to use it as a mode of self-management.

That these results were due to the yoga intervention is highly likely given that most improvements were not sustained to week 12. At week 12, in comparison to the control group, the intervention group had an increase in arm volume of lymphoedema and a decrease in shoulder ROM in internal rotation for the affected arm. It also lost the symmetry in ROM for both arms. Although the intervention group continued to improve in total QOL, it worsened significantly in the sub-scale of function, while the control group improved significantly in the sub-scale of symptoms. Both groups improved significantly in various tissue density scores. Both groups maintained improvements in spinal mobility. Both groups recorded similar results in the strength of the separate muscles throughout the trial.

The improvements experienced by the control group may have been a result of the participants' greater amount of physical activity and attendance at group exercise classes than that of the intervention group.

As most of the improvements made by the intervention group at week 8 were not maintained to week 12, it would appear that a longer intervention was required to sustain those improvements.

7.4 Implications and areas for further investigation

The results of this pilot trial provide further evidence to the extensive literature reporting the safety of exercise for women with BCRL under supervised and progressive conditions. The study also adds further information about the positive effect of gentle exercise and slow breathing on the reduction of tissue density and symptoms.

However, as the current trial had small numbers, trials with larger samples are necessary before conclusions can be made. As most significant between group results occurred at week 8, it appears that the eight weeks of yoga intervention were required to produce these results. A longer intervention may be necessary for significant changes in QOL and spinal mobility to occur. In the current trial, most changes that occurred at week 8 were not sustained to week 12. Longer trials are therefore warranted to test for further effects and to ascertain whether improvements can be sustained.

The increase in physical and mental awareness in the intervention group women may have led to the positive association between their subjective report of sensations and their objective scores for lymphoedema levels. A disparity between self-reporting of sensations and lymphoedema levels is more commonly reported in the literature, so this may be an area for future research into yoga and BCRL.

It was difficult to draw definite conclusions about the association between the level of tissue density and other outcomes such as lymphoedema levels, symptoms, ROM actions in internal rotation and spinal flexion/extension. Further, it could not be firmly concluded whether lymphangiogenesis occurred. As published research associating tissue density with these other areas is limited, further investigation is warranted.

The reduction in pain limiting physical activity that occurred in the intervention group, despite the fact that it had a higher level of actual pain, may be related to the mindfulness practices of yoga, and this too warrants further, specific research.

Although the need to include posture, core stability and symmetry in physical therapies for women with BCRL has been flagged, there is currently very little literature on the topic. The objective and subjective results of this trial suggest that yoga did improve posture, core and shoulder stability and symmetry of shoulder ROM and point to the need for further investigation. These improvements may also indicate that yoga can provide a gentle and rehabilitative return to exercise for women with BCRL and help to counteract the fear that many women have when returning to exercise.

The lack of improvement in the strength actions in horizontal adduction and extension may indicate a need to target these particular actions in future yoga trials for women with BCRL.

As no prior research existed on the effect of yoga on BCRL, the current trial used many measures to identify the vital areas of change that resulted from the yoga intervention. Future trials could focus on specific areas.

As far as the principal investigator could ascertain, this is the first study of spinal mobility in women with BCRL. While the results indicate that there may be some benefits to spinal mobility from yoga intervention, further research in this area is needed and the connection between spinal mobility, shoulder ROM and tissue density should also be investigated.

Many outcomes of the current trial supported the findings of other studies. As in other studies on women with BCRL:

1. The risk factors for lymphoedema were mastectomy, axillary node dissection, a high number of nodes removed, post-operative infection, a high level of adverse effects from treatment and a high BMI;
2. There seemed to be a relationship between levels of lymphoedema and upper body function;
3. Grip strength was not impaired in either group (apart from an unexplained reduction in the control group at week 12).

As in other exercise studies on women with BCRL and yoga studies for women with breast cancer:

1. The intervention participants reported the enjoyment gained from the group dynamic;
2. The intervention participants reported that the emotional and physical effects of breast cancer diagnosis were strong.

As in other yoga studies, including those for women with breast cancer:

> The intervention participants reported improvement in physical, mental and social areas of their lives, particularly the development of physical and mental awareness, increased calmness and improved wellbeing, sleep, relationships and physical function.

7.5 Significance of the study

The current trial has provided novel research findings on the effect of yoga on women with BCRL.

First, based on the positive results obtained for this cohort of Tasmanian women, yoga was effective in reducing affected upper arm tissue density, symptoms and pain limiting activity and in creating symmetry in shoulder ROM and pelvic stability, without at any stage exacerbating the lymphoedema. The actual yoga and DVD were reported as being highly effective and provided women with "time for self." Further, the women improved in their physical and mental awareness, calmness, physical function and posture, relationships and gained a high degree of satisfaction from the group dynamic. This may be why nine women reported on a significant change that had occurred in them from participation in the intervention.

Second, these outcomes, as well as the other reported findings, reveal that further research is warranted. Suggestions have been made for possible areas of future research as well as for improvements in methods.

Third, the findings of the current trial can be used to develop guidelines to help yoga teachers when they are teaching women with BCRL, within the growing specialisation of yoga therapy. Researched information can be provided for teaching methods, necessary precautions, possible benefits and individual variations and needs. As the aim of yoga therapy is to enable the individual to live to their full potential with whatever condition they have, this information is vital.

Until further studies are undertaken health care providers are not yet able to recommend yoga as another practice for women with BCRL.

7.6 Recommendation

It is therefore recommended that:

1. Further trials into the effect of yoga on women with BCRL be undertaken;
2. Trials be held with longer intervention and larger samples;
3. These trials focus on specific physiologic areas such as spinal mobility;
4. A trial on the use of the DVD as a self-management tool for remote women be undertaken;
5. Guidelines for teachers of yoga be developed.

7.7 Concluding statement

The current trial was a direct result of the need to evaluate the effect of yoga on women with BCRL as no published research existed. While teaching yoga to women with BCRL on the Northern Beaches of Sydney over the previous 15 years, the principal investigator was continually being advised of the many improvements from yoga in relation to the women's physical and emotional effects of having lymphoedema and their upper body functioning. The positive results of this trial have indicated that these improvements were genuine and that yoga may provide another option for women's self-management of BCRL.

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APPENDICES

APPENDIX A

PARTICIPANT INFORMATION SHEET

RESEARCH - UTAS

The Effect of Yoga on women with secondary arm lymphoedema as a result of breast cancer treatment – a pilot randomised controlled trial.

This study will be undertaken in partial fulfilment of a Masters degree for Annette Loudon

Invitation

You are invited to participate in a research study into the effects of yoga on women with secondary arm lymphoedema from breast cancer treatment.

We are interested to see if yoga helps reduce arm lymphoedema and improves: the mobility, stability and strength of your affected arm; mobility of the upper spine; and your sense of well-being.

The study will be conducted by Annette Loudon, an experienced, qualified and accredited yoga teacher. For this study, we are seeking women who have:

- completed all treatment for breast cancer at least 6 months ago other than hormone therapy;
- lymphoedema in one arm (only) and;
- Are over 18 years of age and self-managing the lymphoedema.

You will **not be eligible** to participate in this study if you are currently receiving:

- Complex Lymphoedema Therapy (CLT)
- Medical treatment for cancer, an infection or a mental health condition.

Women who are pregnant and those with pacemakers are also not eligible.

This research is being supervised by

Associate Professor Tony Barnett
The Director of Rural Health UTAS

Professor Neil Piller
The Director of the Lymphoedema Clinic and Head of Lymphology, Flinders University SA

Dr Maarten Immink
The Head of Human Movement, Uni of SA

Dr Andrew Williams
Senior Lecturer: School of Human Life Sciences UTAS

What is a pilot randomised controlled trial?

This means that we will allocate you to an intervention group or a control group. In this study the intervention is yoga. The method of allocation into groups is done so that there is an equal chance of you being in either group. However, both groups will have the yoga. The control group has the yoga after the intervention group finishes.

We then take the same measurements before the study and at weeks four, eight and a month after the study. The yoga will be taught as a class for eight weeks.

These measurements will involve you filling in some questionnaires about your health, breast cancer treatment, lymphoedema, quality of life and physical activity. You will have your arm lymphoedema, arm mobility and strength measured. We will also record your height and weight. You will be asked how your arm feels and how it has affected you.

The yoga group will complete a diary of home practice and have an interview about other effects of yoga, at the end of the study. You can choose if you would like to have your spinal mobility tested.

Who will do the measuring?

You will be measured for lymphoedema every four weeks by professional lymphoedema physiotherapists. Final year Human Life Science students will be trained for the arm mobility and strength measurements.

What is the yoga group?

The yoga will consist of eight weekly yoga sessions, for one and a half hours, from 5:45 pm to 7:15 pm in March and April 2011.

You will be given your own DVD which will have a 42 minute yoga session. You will be asked to do this daily. This DVD has been made especially for this study, it is not available commercially.

In Hobart (H) the yoga will be held on a Tuesday evening at the Hobart Women's Health Centre, North Hobart. In Launceston (L) the yoga will be held on a Thursday evening at the Launceston Community Health Centre, Kings Meadows. There is parking at both venues.

What are the dates?

The first measurements will be on Feb 22(H) or 24 (L); Week four will be March 29(H) or 31(L);

Week eight will be April 26 (H) or 28 (L);

Final measurements will be May 17(H) or 19(L).

You will be given the same time at each measuring, and it will take about 45 minutes to an hour.

What if I have never done yoga?

You don't need any experience. The yoga consists of breathing, some gentle movements, some meditation techniques and relaxation.

Modifications will be made for you if needed. You can sit in a chair or lie on the floor. You only need to move your body in a way that is comfortable for you and causes no pain. In fact, this is the whole philosophy of yoga.

What if I am in the control group?

For now, you will just go about your normal life, but without any yoga. You will receive yoga at a later date. You will have all the other measurements and quality of care as the yoga group. You will also be given the DVD after the study.

Management of arm lymphoedema

Both groups will be given a current best practice information sheet on management of secondary arm lymphoedema.

What if my lymphoedema flares up during the study?

We hope this does not happen; however if it does, you will be advised to seek your preferred treatment immediately. You can still be part of the study but your information will no longer be recorded. You will be asked to continue with your current self-management of lymphoedema and also be given guidelines on the current best-practice for self-management of lymphoedema.

Is this voluntary?

Absolutely. It is important that you understand that your involvement is voluntary. While we would be delighted to have you participate, we respect your right to decline. If you decide to discontinue participation at any time, you may do so without providing an explanation and without consequences. All information will be treated in a confidential manner, and your name will not be used in any publication arising out of the research.

What happens to the research?

Paper-based data from the research will be stored in a locked cabinet in the University Department of Rural Health for five years after publication, then destroyed in accord with university protocols. In any publication, you will not be identifiable. Other data for analysis will be kept on a password protected spreadsheet on computer.

Are there any possible benefits from participation in this study?

This is a research study to identify the possible benefits of yoga for women with lymphoedema. As a research project we cannot state that any benefit will occur. The possible benefits may be that: lymphoedema does not become worse or decreases; arm and spinal mobility improves and that quality of life improves.

If the trial proves successful, women will have another way they can safely manage their lymphoedema.

The use of the home-based DVD will also provide information about whether this method of delivery can be used for rural and remote women in Australia in the future.

Are there any possible risks from participation in this study?

The aim of yoga is to do no harm and to enable people to move and progress at their own level. This will be reinforced each week. Your physical movements will be individualised to ensure you do not harm yourself. You will be able to do the movements in a chair if that is better for you.

The yoga in this study is very gentle and any contra-indications you may have will be managed to ensure your safety. Harm is highly unlikely.

Risks of arm lymphoedema will also be managed by following the guidelines set out by the National Lymphoedema Network (NLN) in its Position Statement on Risk Reduction Practices 2010 (www.lymphnet.org).

In carrying out the measurements, the floor will be clear and tidy, and measuring equipment stored appropriately so that no tripping occurs. Lighting will be adequate and any cords will be taped. All staff are qualified and experienced in the measurement procedures and they have undergone further training especially for this study.

The venues for this study follow OH&S guidelines. Parking is close by. Any mobility problems will be discussed and managed.

If you should become concerned or distressed about anything, you can contact the researcher or a person from the university ethics committee. These contact details are below.

You may also contact a breast care nurse (at no expense) should you wish to discuss any concern about the study or to obtain further advice. Breast care nurse contact details are also listed at the end of this document.

What if I have questions about this research?

The researcher will be happy to discuss any aspect of the research with you.

Can I find out the results of this research?

Once we have analysed the information, we will mail / email you your individual results and a summary of the overall findings. You are welcome to contact us at that time to discuss any issue relating to the research study.

Has this study been approved?

Yes, this study has been approved by the Tasmanian Social Science Human Research Ethics Committee. If you have concerns or complaints about the conduct of this study, you should contact the Executive Officer of the HREC. (03) 6226 7479 email human.ethics@utas.edu.au.

You will need to quote [*H0011534*].

Thank you for taking the time to consider this study.

- **Should you need further clarification please contact Annette Loudon.**

- **If you wish to take part, please sign the attached consent form and send it in the enclosed envelope.**

This information sheet is for you to keep.

Best wishes,

ANNETTE LOUDON

Contact numbers:

Annette Loudon
Masters by Research student Rural Health
UTAS
03 63244031
aloudon@postoffice.utas.edu.au

Executive officer
Human Resources
Ethics Committee
UTAS
03 6226 7479
human.ethics@utas.edu.au

Breast care nurses

Your local breast care nurse has agreed to speak to you at any time during the course of the research should you need to speak to her about any worries or concerns:

Hobart
Julia Aston(Julia.Aston@dhhs.tas.gov.au) 62227602
Karen Sprigg (karen.sprigg@dhhs.tas.gov.au) 62164335 0400494646

Valerie Smith
(Valerie.Smith@dhhs.tas.gov.au) 62227602

Launceston
Sue Schwabe
(susan.schwabe@dhhs.tas.gov.au) 63365535

APPENDIX B SAMPLE OF RECORD FORMS

(Medical Questionnaire; Lymphoedema; Shoulder ROM; Spinal ROM)

The Effects of Yoga on women with secondary arm lymphoedema from breast cancer treatment. A Pilot Trial.

- *This information is to ensure that we are aware of your health and get a picture of your treatment for breast cancer and lymphoedema.*
- *All information is condfidential.*

▪ *Should you have any queries about your health please check with your doctor.*

The first page is about your general health

Name:_____Address:_____

Phone:_____email:_____

Age:_____Country of birth:_____

What is your highest educational qualification?_____

Do you live alone? Or with another person/people?_____

Are you a member of any organisations, if yes please list:_____

_____

Current occupation:_____

Please state occupation pre-surgery if different:_____

Hobby:_____

Degree of fitness:_____

Current other exercise_____

Emergency contact (name, relationship and phone number):_____

General medical conditions

Known general physical conditions:	**Yes**	**No**	**Comment if necessary**
Arthritis			
Asthma			
Dizziness			
Diabetes (type 1 type 2)			
Glaucoma			
Headaches			
Heart condition			
Hernia			
High blood pressure			
Low blood pressure			
Middle ear problems			
Previous surgery			
Thyroid problems			

- Please describe any musculo-skeletal problems you had prior to or since your surgery that are not related to the surgery such as neck, shoulder, hip, knee, ankle or back. It may be pain or conditions. Please list any treatment if applicable. What makes it better or worse?

_____

_____

- Other conditions not listed above (please be specific).

_____

_____

- Medication:

_____

The second page is about your treatment for breast cancer

(I apologise for reminding you of this time in your treatment, again it will give me a profile of your body so I know how best to help you in your yoga)

Date of surgery:_____Hospital:_____

1 Type of breast cancer (please circle):
Ductal carcinoma in situ / lobular carcinoma in situ / invasive carcinoma / other (please describe):
_____

2 Stage of breast cancer if known (please circle):
0 I II III IV

3 Surgery (please circle):
Breast conserving surgery (lumpectomy, complete local excision, partial mastectomy, wide local excision)/mastectomy (modified radical mastectomy). Lumpectomy followed by mastectomy.

4 Which side (please circle):
left / right / both

5 Lymph node dissection (please circle):
Axillary lymph node dissection/Sentinel lymph node biopsy.

6 Number of nodes sampled_____

7 Number of positive nodes_____

8 Did you have chemotherapy (please circle)? Yes /No
If yes
Please explain any adverse effects_____

9 Did you have radiotherapy (please circle)? Yes / No
If yes
Please explain any adverse effects_____
if yes
Which part of the body had radiotherapy (please circle):
Axilla / chest wall / neck / sternum / other (please describe)_____

10 Did you have or are you currently having hormone therapy (please list and describe)?

_____

_____

11 Did you have or are you currently having targetted therapy eg Herceptin® (please list and describe)?

_____

12 Are you having any other treatment? Can you please describe it?

_____

_____

13 Please describe any effects from any of the treatments you are still taking?

_____
_____

14 Did you have any a. infections after your surgery or during your treatment? (please list and describe)? b. Or cording?

_____

15 Did you have fluid removed from the wound site after surgery?_____

16 Have you had a breast reconstruction, if so where was the tissue taken eg back, stomach etc?

_____

The next pages are about your treatment for lymphoedema

This will help me get a picture of how your body and lymphoedema react.

1 How long have you had lymphoedema?_____
2 How long after your surgery did you get it?_____
3 Do you have lymphoedema of the trunk/breast?_____how is it treated?
_____
3 Can you describe your first treatment for lymphoedema?_____
_____
4 Can you describe your treatment since then and now?_____
_____
_____
5 Are you currently having any treatment? Please describe it._____
_____
6 Is it your dominant arm that is affected ? (ie the arm you use to open a lid, or throw a ball, it may or may not be the arm you write with.) _____
7 Can you describe the sensation of your arm when you feel you have done too much?
_____
_____
8 What alleviates this feeling?_____
_____
_____
9 Do you feel pain in your arm or shoulder very often from your lymphoedema, do you know what actions cause that?_____
_____
10 What lessens this pain?_____
_____
11 Do you ever feel embarrassed or do you lack self-confidence due to your arm? When?
_____
12 Does your lymphoedema ever stop you doing something that you want to do. Can you describe what that is._____
_____
13 a. Do you wear a compression sleeve? b. Does it help your lymphoedema?
c. Does it cause embarrassment?_____
_____
14 Please describe how you self-manage your lymphoedema.
_____
_____

15 Please describe what makes your lymphoedema worse.
_____
_____

16 Do you feel your lymphoedema affects you in any other way you would like to descibe._____

_____

_____

17 Are there physical activities that you choose NOT to do out of fear that it may make your arm worse? Can you explain what they are please.

_____

_____

_____

17 Do you feel you have much stress in your life? _____

18 Does your lymphoedema make this worse?_____

19 Is there anything else you would like to say about the effect of lymphoedema on your arm or your life?

_____

_____

_____

Thank you for filling in all these forms!

Your contribution is appreciated and will continue to add to the research information on lymphoedema and its effect on women's lives.

Annette Loudon
Masters by research student
Department Rural Health
UTAS

03 63244031
aloudon@postoffice.utas.edu.au

Lymphoedema Assessment

Baseline measurement

ID_____date_____location_____assessor_____

_____

A to complete later Weight: _____Height _____ Age: _____

Dominant hand ☐ Right ☐ Left ☐ Ambidextrous

Side of swelling **Arm**☐ Right ☐ Left **Brea**st ☐ right ☐left **Chest** ☐ right ☐left

Skin condition: good dry extremely dry ulcerated fistulas fungal infection **Pitting:** yes no

Area: hand forearm upper arm chest

Remove all jewellery (rings are ok) and wipe with swab to remove moisturiser etc. All positions are supine.

1 Bioimpedance

Say aloud as you apply each electrode; check body is relaxed and arm and leg are not in contact with the body, put something under armpit or between legs if necessary, green line always proximal. Do affected arm first.

	Affected	**Non-affected**	**L-Dex** (lymphoedema index)	**Comment**
R (resistance)				
Xc (reactance)				

2 Tape (circumference)

Position of participant:_____Variation:_____Arm:_____

Person supine, arm by side and pronated.

Firm but able to move tape

	Affected	**Non-affected**	**difference**
MCP (mid-point)			
Ulnar styloid (distal)			
10cm			
20cm			
30cm			
40cm			
50cm			
60cm			
70cm			
sum			
% difference			
Fingers	**Right**	**Left**	**difference**
thumb 1			
2			
3			
4			
5			

Comments:

_____

_____

_____

3 Tonometry

Mark person at required places.

Person relaxed, don't force or hold on top of tonometer. After beep say measurement aloud, count one, two then repeat.

Comment:

Position		**Non-affected**	**Affected**	**Difference**
		Electronic	**Electronic**	**Electronic**
Mid forearm	Meas 1			
	Meas 2			
	Meas 3			
Mid upper arm	Meas 1			
	Meas 2			
	Meas 3			
Anterior trunk	Meas 1			
	Meas 2			
	Meas 3			
Posterior trunk	Meas 1			
	Meas 2			
	Meas 3			

Data entered by:_____date:_____

Arm ROM Grip strength Assessment
Baseline measurement

Participant ID _____

Date of Assessment_____

Location_____

Assessor_____

Side of swelling ☐ Right ☐ Left

Demonstrate to person how to do it, check shoulder and neck remain stable. Do non-affected arm first then affected arm in turn three times. Allow to rest between moves if necessary. Maintain stability of shoulder girdle, stop at rom or pain or discomfort.

1 ROM

Instrument_____measured in degrees

Shoulder movement	Non-affected arm				Affected arm			
	Trial 1	Trial 2	Trial 3	BEST	Trial 1	Trial 2	Trial 3	BEST
Flexion								
Internal rotation								
Extension								
Abduction								
External rotation								

Comment:_____

_____

_____

2 Grip strength

Instrument_____grip distance_____

Measured in kg

Muscle	Affected arm				Non-affected arm			
Grip strength	Trial 1	Trial 2	Trial 3	BEST	Trial 1	Trial 2	Trial 3	BEST

Comment:_____

_____

_____

Ask woman to open and close hand, swing and move arm at end to ensure lymph flows again.

Data entered by:_____Date:_____

Thoracic spine measurement
Baseline measurement

Participant ID _____
Date of Assessment_____
Location_____
Assessor_____

Remember to say person's name and date on camcorder and add any info eg if they do it more than three times or stop for pain and can't continue test.

Number on video:_____

Saved as:_____

Introduction:_____Time:_____

_____

Weight: _____Height _____BMI (if known) : _____ Age:

_____

Dominant hand ☐ Right ☐ Left ☐ Ambidextrous

Side of swelling ☐ Right ☐ Left ☐ Breast

Comment: (eg how many tests, difficulties etc)

_____

_____

_____

_____

_____

Distance between Markers: measure first time

LSPIS – RSPIS _____ LACR-RACR_____T1-T6_____

T6-L1_____ L1-L3_____L3-S1_____

Spinal movements – spinal markers on pegs, acromion normal

Demonstrate first.

Maintain stable position, stop if pain, instability, range of motion. Repeat 3 x.

Heels on mark on floor

Movement	**tick when recorded**		
Flexion Stand - knees soft, chin in, contract abs			
Extension Stand - arms crossed at chest, chin in			
Add markers on pegs SPIS			
Lateral flexion left Arm slides down/little finger touches leg			
Lateral flexion right Arm slides down/little finger touches leg			
remove spine markers			
Rotation to the left Sit - pelvis shouldn't move			
Rotation to the right Sit - pelvis shouldn't move			

Data entered by:_____**date:**_____

APPENDIX C THE YOGA INTERVENTION

Yoga class for women with breast cancer-related lymphoedema (BCRL)

The effect of yoga on women with secondary arm lymphoedema from breast cancer treatment. A pilot trial.

Annette Loudon
Masters by Research, Rural Health
UTAS
March and April 2010
Launceston and Hobart

1 Background and supporting evidence

Yoga was taught according to the Satyananda Yoga® [1] style of teaching to ensure conformity with an established method of teaching. The yoga class was 90 minutes, once a week for eight weeks. The home-based practice was by following a 42-minute DVD specifically made for this intervention, based on but shorter than the weekly class.

The yoga class was based on the following principles:

1.1 Breathing at the commencement and conclusion of the class

Breathing is an important aspect of yoga and lymphoedema management. Slow, deep breathing, with breath retention, was used to create pressure changes to empty the lymphatic system into the venous system at the lymphatic ducts and clear the lymphatic pathways, before the postures commenced and again when they were completed [2-5]. This breathing also balances the sympathetic and parasympathetic nervous systems [6-7]. A chant, with a prolonged exhalation following a deep inhalation, commenced and finished each yoga class to enhance the emptying of the lymphatic ducts [8-9].

The long, slow breath may also improve the elasticity of the secondary muscles of inhalation, such as the serratus anterior, pectoralis major and pectoralis minor [10], that can be impaired from surgery and radiation in breast cancer treatment [11-12]. Fibrous tissue in the chest and upper back, caused by surgery, radiation and lymphoedema [13-14], may also be softened by slow breathing, as was reported in a *tai-chi* study [3].

1.2 Physical postures-general principles

The physical postures of yoga (*asana*) focussed on correct placement of the body, stabilisation of the joints and movement according to kinematic chains in order to reduce the impairment that can occur from breast cancer treatment, fibrosis and lymphoedema, in particular at the shoulder girdle [11-12, 15-16], thoracic spine [17] and neck [18]. Core stability was also focussed on, as has been recommended for women after breast cancer treatment [19]. Improved movement patterns may also help to reduce the swelling and fibrous tissue caused by lymphoedema, according to the results of one case-study of lower limb lymphoedema [16]. Postures in the current trial were performed while supine, seated or standing.

Before any movement commenced, irrespective of body position, the body was first aligned to promote postural awareness, called *kaya sthairyam* [20]. This was important, as faulty posture can

exist in women after breast cancer treatment and as a result of lymphoedema [12, 21]. Next, stabilisation of the pelvis and joints was ensured by the use of *bandha* [22]. For example, *moola bandha* and *uddiyana bandha* created core stabilisation by co-contraction of the pelvic floor and transversus abdominis muscles, and internal oblique when required [23]. *Amsa bandha* created stabilisation of the thoracic-scapulohumeral joints by co-activating opposing muscles such as the glenohumeral abductors and adductors and scapulothoracic protractors and retractors, depending on the shoulder action [22]. Further, movement patterns followed kinematic chains of progressive muscle contraction; for example, rotation of the spine engaged the internal oblique, then the external oblique, serratus anterior, rhomboids, trapezius, and pectoralis minor, so that the body rotated in a stable and biomechanically efficient way [24].

Coordination of each posture with a slow and steady breath, which is one of the unique characteristics of yoga [25-26], was emphasised during the physical movements. It was believed that this would aid lymphatic clearing as well as provide a mental focus. In this way, the physical practices aimed to not only improve physical functioning but also develop mental awareness.

1.2.1 Moving Postures in the class

Propulsion of lymph is a function of muscle movement and breathing [27]. The order of the moving postures was chosen to promote the clearing of lymph nodes from proximal to distal, following the principles of manual lymphatic drainage (MLD) [2, 28]. Each series of postures was slow and rhythmical and was followed by an adequate rest period to engage the parasympathetic nervous system [29] and allow adequate emptying of lymph vessels [28, 30].

Yoga movements were used to open collateral pathways after clearing the nodes in that area, enabling the lymph to flow from the affected area to functioning nodes, either at the opposite axillary nodes or the ipsilateral inguinal, in keeping with the principles of MLD [2].

The lymphatic ducts continued to be cleared, following the principles of MLD, by using yoga postures that combined a long, slow exhalation with contraction of the abdominal muscles [2, 31].

Gentle, systematic movements based on range of motion of the neck, shoulders and thoracic spine were used in the postures, accompanied by the long, slow breath, to create gentle stretching and compression of the tissue in the arm, chest and upper back and to encourage vascular and lymphatic flow [13-14] and perhaps reduce the fibrous tissue in these areas, as occurred in a *tai-chi* study [3].

1.2.2 Held Postures in the class

Standing, held postures, including balances, were used to improve core stability [23, 32], balance, strength and symmetry, all of which can be compromised by breast cancer treatment and lymphoedema [33-34]. The length of time women remained in the held balance increased over the course of the trial, following the guidelines advocated for women with BCRL [35]. No weight-bearing on the arms was introduced.

1.3 *Pranayama*

The *pranayama* technique of alternate nostril breathing (*nadi shodan*, but also known as *anuloma viloma*) was performed after the postures to cool the body and calm the mind by balancing the sympathetic and parasympathetic nervous systems [28, 36], and as a preparation for meditation [1].

1.4 Meditation practices

As holistic practices have been recommended for women with BCRL in order to improve aspects of quality of life (QOL) that can be affected by living with lymphoedema [37], two types of meditation

were used. First, the Satyananda™ mindfulness practices known as *antar mouna*, which are part of *pratyahara* or withdrawal of the senses, were used. They have been described as helping individuals to accept the current situation [38] and to recognise their personal reactions and attitudes and so lessen the effects of negativity that can be associated with those reactions [39]. In research trials, mindfulness practices have been shown to improve mood, reduce stress and improve immune function [40-42], all of which could be of benefit to women with BCRL.

Second, focussed meditation known as *tratak* (candle gazing) was introduced in the final two weeks of the yoga class. This type of meditation is part of the practices known as *dharana* (concentration) and *dhyana* (contemplation). In yoga research trials, its use has resulted in improved concentration, reduced stress and removal of negative thought patterns [43-44]. These benefits may also be transferrable to women with BCRL.

1.5 Deep relaxation with elevation of the affected arm

Arm elevation was used during the relaxation practices to decrease venous flow and reduce lymphoedema [5]. Relaxation known as *yoga nidra* (systematised by Swami Satyananda) was used to cool down the body and to decrease the response of the sympathetic nervous system, leading to slower heart rate and lower arterial blood pressure, which, in turn, slows the propulsion of lymph [27]. This "relaxation response" is used therapeutically to improve the recovery process in many health-related issues [45]. Relaxation has also been recommended for improving QOL in women with BCRL [46-47]. Relaxation is considered another practice of *dharana* and *dhyana.*

1.6 Group discussion

The group discussion at the conclusion of the class provided an opportunity for women to discuss their home-practice and any difficulties or issues they had during the class, and to ask questions about yoga in general while learning a little about yoga philosophy. It also provided an opportunity for the development of a group dynamic. Group and personal responsibility are the practices of yoga known as *yama* and *niyama*, respectively.

Many studies on the effect of yoga on women with breast cancer have reported on the benefits gained from a group discussion [48-50]. The enjoyment and positivity derived from simply being part of a group of women who have been through the same treatment have also been reported in yoga and breast cancer studies [51-53] and in exercise studies on women with BCRL [54-55]. Such group interaction may provide the support that women with BCRL say is of positive benefit to them [56].

The women decided whether to wear a compression sleeve or not, but were advised to wear it after yoga [57]. Women were also advised to not wear narrow bra straps [58]. Modifications for other conditions, as well as for the lymphoedema were given. The room was kept at a constant temperature.

2 The yoga class (including the stage as defined in *The Yoga Sutra* of Patanjali [59]).

Red denotes practices on the DVD

2.1 Welcome and brief check of how women are **5 minutes**

2.2 Breathing **10 minutes**

Starting position with eyes closed

1. Lying, knees bent to 90°, or straight or supported by cushion, palms by side, neutral spine

OR

2. Sitting, palms on lap, left palm on top of right palm

Same practices though briefer

Practice	Sanskrit/Patanjali stage	Description and Modification	Purpose
Settling with awareness	Kaya Sthairyam Pratyahara	Be aware of body, mind, emotions, day so far and day to follow, accept them and on three slow breaths, let them go; Be aware of the body; Visualise the body from all angles; Bring stillness to the body.	Preparation for yoga; Postural awareness; Mindful awareness.
Awareness of present moment	Antar mouna level one Pratyahara	Bringing awareness to the present moment; be aware of clothing, air on skin, sounds.	To bring focus to the present moment, and let go extraneous thoughts, sensations; Develop witness aspect.
Abdominal, thoracic, clavicular breathing	Pranayama	Breathe into and out of lower ribs; Breathe into and out of middle ribs; Breathe into and out of upper ribs; Repeat each 3x	Movement of ribs and tissue in different areas; Preparation for full yoga breath; Mindful awareness of breathing.
Full yoga breath		Breathe into lower, then middle, then upper ribs Breathe out of upper, then middle, then lower ribs Lengthen and slow down breathing Add slight contraction of moola bandha (pelvic lock=contraction of pelvic floor and transversus	Mindful awareness of breathing; Calm the mind, balance the nervous system; Empty the lymphatic ducts and encourage the flow of lymph to empty vessels; May stretch tissue affected by breast cancer surgery, i.e. pectoral muscles,

	Pranayama	abdominis muscles) Begin to add slight pauses after inhalation and after exhalation	serratus anterior; May reduce fibrosis from scar tissue, radiation and lymphoedema.

2.3 Yoga postures-*Asana* **35 minutes**

a Starting position

1. Lying, knees bent to 90°, palms by side, neutral spine
   OR
2. Sitting, palms on lap, left palm on top of right palm

Bi = breathe in Bo=breathe out

b Each posture followed by equal time of rest, to engage para-sympathetic nervous system, fully empty lymphatic vessels before the next series of movements and promote awareness of sensations.

Practice	Sanskrit- all Asana	Description and Modification	Purpose
1a Neck turns	Greeva Sanchalana	Bi rotate neck to affected side, Bo centre, Bi rotate neck to other side, Bo centre. Repeat with pauses after breath. 2x	Warm up neck ; Establish breathing pace; Focus on awareness (physical and mental); Clear supra-clavicular nodes.
1b Add outward rotation of opposite arm		Bi roll neck to affected side while stretching opposite arm to side with clenched fist, hold breath, Bo neck to centre, hand to stomach with extended fingers, repeat to other side 5x	Warm up neck, chest, upper back, arm and hand; Clear supra-clavicular nodes; Encourage lymph emptying to axilla from pressure change with clenched fist.
2 Leg slides	Utthanpadasana - variation	Bi slide affected leg away, dorsiflex foot, Bo point toe, bring back to starting position; Maintain pelvic stability and *moolabhanda*; Repeat other side. 2x	Warm up leg, foot, lower back, abdominals;

3 Knee hugs – leg lock pose	Supta Pawanmuktasana	Affected side – knee held at chest Bi arms straighten, knee goes away from chest, dorsiflex foot, arms straighten, Bo point toe, bring knee back to chest, arms bend 5x each leg	Warm up leg, knee, foot, lower back, abdominals; Clear inguinal nodes.
4 Shoulder circles	Skandha Chakra	Fingers on shoulders. Be careful of hand position especially for women with hand lymphoedema. Slow shoulder circles, one way then the other. Bi elbows away from centre, Bo towards centre 5x each way Double arm circles, arms stay parallel, hands on shoulders or opposite elbows.	Warm up shoulders, arms, chest, upper back Clear axillary nodes on both sides. Warm up spine, clear sternum and rib nodes.
5 Bent arm opening, chest towards knees	Naukasana – variation combined with namaskarasana –variation of arms	Elbows, forearms together at chest Bi open arms, elbows bent, make fist, pause breath, Bo chin to chest, tighten abdominals, spread fingers, palms together, arms straighten in front of body then back to starting position, pause breath. OR Bo chin to chest, tighten abdominals, bring chest to knees, spread fingers, palms together, arms straighten, then back to starting position, pause and lower. Backward rotation of pelvis in both moves on Bo to engage psoas muscle and help to empty inguinal	Warm up whole back and front of body Clear deep lymphatic ducts and inguinal nodes.

		nodes. Repeat 5x	
6 Lying Archer	Akarna Dhanurasana - variation	Hands in prayer position (*pranam mudra*) at heart centre. Bi make fist, rotate upper body to affected side, pause with breath, Bo both hands sweep across chest to other axillary nodes, pause. Repeat 5x	Continue to warm up and mobilise spine and upper body. Open collateral lymph pathway to opposite axillary nodes.
7 Lying rotation	Supta Udarakarshanasana - variation	Knees bent a little further away and wider than hips, arms out at shoulder height or where comfortable. Bi drop knees to opposite side from affected arm and lengthen knees away, make fists, and move neck to affected side, pause with breath, Bo back to starting position, sweep hands down to inguinal on affected side. Repeat 5x	Continue to mobilise spine and body. Open collateral pathway to inguinal nodes on affected side.
8 Arm/leg stretch	Supta Pawanmuktasana	Stable starting position. Bi stretch affected side, arm to ear or wherever possible in stable position and leg along floor, hand clenched, foot dorsiflexed, pause with breath, Bo bring knee to chest, and if possible forehead to knee, fingers around knee and toe pointed.	Continue to mobilise body, strengthen abs, stabilise shoulder movements, movement of tissue at chest. Pump lymph from distal to empty nodes. Empty lymphatic ducts.

		Repeat on other side, i.e. alternate 5x	
9 Sitting rowing	Nauka Sanchalanasana	Sitting in appropriate position, on cushion or knees bent if appropriate, legs at hip width, hands in pranam mudra at heart centre. Bi stretch arms to where possible overhead, and to front of body, fists clenched, straight spine, pause with breath, Bo sink into hips, bend elbows, fingers stretched, pause with breath, come back to starting position. 5x each way	Continue to mobilise body, strengthen abs, stabilise shoulder movements, movement of tissue at chest. Clear deep lymphatic ducts, while encouraging lymph to flow towards axillary nodes and collateral pathways.
10 Standing archer	Akarna Dhanurasana	Standing affected leg slightly forward, hands in *pranam mudra* at heart. Bi rotate to affected side into archer, fists clenched, pause with breath, Bo sweep open palms across chest, pause with breath, back to starting position. Repeat 5 x	Strengthen and stabilise body in standing position, stabilise and mobilise shoulders and mobilise thoracic spine, movement of tissue at chest. Clear collateral pathway on non-affected side.
11 Modified rope climbing	Rajju Karshanasana - variation	Standing in stable position, arms in *pranam mudra* at heart centre. As if playing a harp or picking an orange, 3 movements going up harp and 3 movements coming down harp Bi reach to front at waist height, twist hand as it closes, pause with breath, other arm goes back into extension beside and behind body, fist clenched.	Strengthen and stabilise body in standing position, stabilise and mobilise shoulders and mobilise thoracic spine, movement of tissue at chest. Encourage lymph flow to axilla.

		Bo arms comes back to body and palms brush at heart centre, pause with breath. Repeat with opposite arms. 2nd movement is at shoulder height, and 3rd movement is above shoulder. Body will twist, hips remain stable. Repeat 3 movements up, and 3 movements down.	
12 Modified arm raise, knee bend	Tadasana - variation	Bi raise arms in front of body, make fists, pause Bo spread fingers, lower arms, as bend knees, torso erect, sweep affected hand down affected side to inguinal nodes Neck follows movement of arms	Strengthen and stabilise body in standing position, stabilise and mobilise shoulders and mobilise cervical and thoracic spine, movement of tissue at chest. Flow of lymph from hands to axilla; Clear axillary nodes; Clear inguinal nodes.
13 Modified side bend	Trikonasana - variation	Standing in stable position, arms beside body, palms Bi side bend away from affected side, make fists, non-affected arm slides down side, affected arm bends at elbow, up affected side, not touching side of body, pause Bo affected arm slides down, fingers spread, sweeping from under arm to inguinal on that side, pause Neck follows direction of arm sliding down leg Repeat on other side without sweep of arm 5x	Strengthen and stabilise body in standing position, stabilise and mobilise shoulders and mobilise thoracic spine, movement of tissue at chest. Feel symmetry of body. Encourage lymph to flow to collateral pathway to inguinal nodes; Clear supra-clavicular nodes.

14 Standing rotation	Kati chakrasana	Legs wider than hips, palms in *pranam mudra*. Bi rotate to non-affected side, neck, chest, pelvis, knees, feet, affected arm to non-affected shoulder, non-affected arm to back, pause with breath – stretch body, fists with hands, Bo back to centre, relax hands. Repeat to other side. Repeat 5x	Strengthen and mobilise body in standing position, stabilise and mobilise body, shoulders and spine, movement of tissue at chest. Feel symmetry of body. Encourage lymph to flow and clear from supra-clavicular nodes.
15 Standing Cat	Marjari-asana - variation	Standing in stable position arms by side. Bi arms back, fists, lift chest, extend spine and neck slightly, pause with breath, Bo arms forward, bend knees, flex spine and neck, fingers spread and overlay each other on stomach, backward rotation of pelvis to engage psoas, pause with breath. Repeat 5x slowly	Begin to cool down body. Moving tissue at chest. Mobilisation of shoulders and spine. Empty inguinal nodes and deep lymphatic ducts.
16 Modified one- legged prayer balance	Eka Pada Pranamasana	Use wall, come into appropriate position non-balancing leg outwardly rotated, foot on floor, or opposite shin or knee, hands in *pranam mudra.* Bi arms open, make fists, pause with breath, Bo arms close to starting position, Repeat 5x each side	Cool down and balance body and mind. Develop strength and symmetry. Encourage lymph to flow distal to proximal.
17 Sitting neck turns	Greeva Sanchalana	Repeat Practice 1a.	Cool down, awareness coming inwards.

			Breathe slowing. Clear supra-clavicular nodes.

2.4 *Pranayama* and preparation for meditation 10 minutes

Sitting comfortably in chair or on floor, supported with pillows, cushions as needed.

All practices but briefer

Practice	Sanskrit/Patanjali stage	Description and Modification	Purpose
Settling with awareness and stillness	Kaya Sthairyam Pratyahara	Be aware of sensations of body; Be aware of the body; Visualise body from all angles; Bring stillness to the body.	Preparation for meditation; Mindful awareness; Cool down body.
Awareness of present moment Sense withdrawal	Antar mouna level one Weeks 1-4 Pratyahara	Bringing awareness to the present moment; aware of clothing, air on skin, sounds	To bring focus to present moment, and let go extraneous thoughts, sensations; Develop witness attitude.
Alternate nostril breathing	Nadi shodan	Use non-affected arm or visualise breath in each nostril.	Calm and balance nervous system; Cool down body.
Mindfulness Sense withdrawal	Antar Mouna level two Weeks 5-8 Pratyahara	Allow images/thoughts to come and go, be the witness.	Develop the witness attitude; Preparation of inner stillness for meditation.
Visualisation One-pointed focus	Visualisation Dharana	Visualise the lymph flowing exactly where it should be.	Develop pointed focus; Use of visualisation as self-healing
Meditation	Tratak	Candle gazing practice (if	Develop pointed focus;

One-pointed focus	Weeks 7 and 8 Dharana Dhyana	appropriate).	Still the mind; Develop meditative technique.

2.5 Deep relaxation **20 minutes**

Sitting or lying, with appropriate pillows for support of body and arm.

Briefer yoga nidra, e.g. breathing backwards 9-1, visualisation on a flower or tree from all angles

Practice	Sanskrit/Patanjali stage	Description and Modification	Purpose
Deep relaxation Affected arm elevated	Yoga Nidra stage one(systematised by Swami Satyananda)(2006) Pratyahara Dharana Dhyana	Structured relaxation – following prescribed order: settling and achieving stillness (Kaya Sthairyam); sankalpa; rotation of body parts, right side, left side, back, front, face, major parts; breathing backwards from 27 to 1; introduction to visualisation – various images; sankalpa; bringing awareness back to the present; finish; Add practice with focus on opposites, eg hot/cold before counting backwards at week 5.	Deep physical, mental, emotional rest; Balance physical, mental, emotional aspects of self; Enable less reactiveness; Lessen stress; Improve immune system; Develop awareness in relaxed state; Considered a relaxation and meditation [60]; Reduce venous flow to slow heart rate and reduce arterial pressure to slow propulsion of lymph (arm elevation).

2.6 Final breathing and chant **2-3 minutes**

Sitting or lying, with appropriate pillows for support of body and arm.

Practice	Sanskrit/Patanjali stage	Description and Modification	Purpose
Full yoga breath.		Breathe into lower, then middle, then upper ribs Breathe out of upper, then middle, then lower	Empty the lymphatic ducts and encourage the flow of lymph to empty vessels before returning to daily

	Pranayama	ribs Lengthen and slow down breathing Add slight contraction of moola bandha (pelvic lock=contraction of pelvic floor and transversus abdominis muscles) Begin to add slight pauses after inhalation and after exhalation	activity.
Chant of the sacred mantra OM three times to complete the class.	Pratyahara Dharana Dhyana		Empty the lymphatic ducts and finish the class with a focussed attitude.

2.7 Discussion **10 minutes**

Yoga themes, yoga, lymphoedema

Patanjali stages of *yama* and *niyama*

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APPENDIX D THEMES FROM THE INTERVIEWS AND LOGBOOKS

Theme

Sub-theme	words	code	no of women	no of comments
Theme one: Physical Outcomes				
1. Lymphoedema	489	1K/1A	15	118
2. Pain	172	1B	12	19
3. Heaviness	66	1L	8	9
4. Arm range of motion	159	1F	7	10
5. Strength	77	1E	6	6
6. Flexibility/Mobility	77	1C/1D	6	11
7. Posture	164	1AB	8	10
8. Other physical outcomes	259	1J/1G/1I/1N	10	68
9. Development of physical awareness	396	1A	15	75
	1859			**326**
Theme two: Mental Health Outcomes				
1. Development of mental awareness	327	2A/2M	12	36
2. Overall wellbeing	100	2B	12	12
3. Equanimity and Calmness	387	2C/2E	15	49
4. Optimism and Self-effectiveness		41 2G	6	12
5. Time for Self	233	2I	12	29
6. Discipline and Control	254	2N/2J	9	15
7. Sleep	272	2D	9	11
	1614			**164**
Theme three: Social Outcomes				
1. Relationships	493	3A	11	25
2. Group Dynamic	979	4A3	15	48
3. Reason for participating/commitment	914	4A4/4B2/4B3/4D	15	159
	2386			**232**
Theme four: The Yoga Phenomenon				
1. Yoga Practice				
(a)A*sana/Postures*	329	4A1i/4A1iv/4B1i	15	43
(b)*Breathing*/*Pranayama*	238	4A1ii	10	16
(c)*Antar mouna*/*Mindfulness*	185	4AIvi	2	2
(d)*Yoga nidra*/*Relaxation*	844	4AIiii	15	64
2. The Yoga Class	772	4A2/5C	15	74
3. The Home Practice DVD/CD	323	4B/4B4	15	27
4. Benefits and Future Intentions	384	4F/5A/5B	15	62
	3075			**288**
Theme five: The Breast Cancer Experience				
1. Breast cancer	**379**	6C	15	**41**
Theme six: Individual Journeys				
in order of priority		6B	9	
LO2JM/LO1PO/LO8DC/H2JM/H14MG/LO11JV/H1SS/H11JW/H4AM				

APPENDIX E FULL RESULTS L-DEX>10 SUB-GROUP: B-8; 8B-12

LDEX>10		Between Group Changes b-8											
	n=8	int-con wk 0				int-con wk 0-4				int-con wk 0-8			
Measure	Varlable	md	CI	CI	p	md	CI	CI	p	md	CI	CI	p
BMI	bmi	4.36	0.82	7.91	**.018*†**	-0.61	-1.17	-0.04	0.143†	-0.41	-0.97	0.16	0.521†
LYMPH	L-dex	-3.35	-7.85	1.16	0.145	1.88	-1.12	4.87	0.22	-1.03	-4.03	1.97	0.5
	armvolume	29.07	-20.42	78.57	0.25	-18.89	-57.94	20.16	0.343	-30.28	-69.33	8.78	0.129
	handvolume	0.54	-2.45	3.53	0.723	-2.55	-5.50	0.39	0.09	0.42	-2.53	3.37	0.781
TON	forearmaff	1.76	-1.81	5.32	0.334	-2.09	-4.98	0.79	0.155	-1.86	-4.75	1.03	0.206
	forearmnonaffect	-0.02	-4.06	4.02	0.992	-0.18	-3.22	2.86	0.908	-1.40	-4.44	1.64	0.366
	upperarmaff	0.09	-4.43	4.62	0.969	-2.16	-5.22	0.91	0.168	-3.20	-6.27	-0.14	**0.04***
	upperarmnonaff	-0.55	-4.35	3.24	0.775	-1.00	-3.80	1.81	0.487	-2.88	-5.69	-0.08	**0.044***
	chestaff	-0.48	-2.37	1.40	0.614	-0.99	-3.16	1.19	0.374	-0.36	-2.53	1.81	0.747
	chestnonaff	0.51	-1.25	2.27	.607	-0.84	-3.32	1.64	0.522	-0.34	-2.82	2.14	0.825
	backaff	-0.26	-3.54	3.02	0.878	1.04	-2.75	4.83	0.592	0.19	-3.60	3.98	0.92
	backnonaff	1.41	-2.31	5.13	0.458	0.41	-2.87	3.69	0.806	-1.42	-4.70	1.86	0.397
VAS	sensations	0.55	-1.04	2.14	0.49†	-0.15	-1.85	1.56	0.822†	-0.55	-2.25	1.15	0.374†
	pain	-0.69	-2.15	0.77	0.357	0.66	-0.11	1.43	0.094	0.06	-0.71	0.83	0.873
	fatigue	0.93	-0.92	2.78	0.323	0.18	-1.21	1.57	0.798	-1.05	-2.44	0.35	0.141
	limitsensation	0.19	-1.38	1.75	0.816	-0.25	-1.67	1.16	0.725	-0.18	-1.60	1.23	0.801
	limitpain	0.16	-1.13	1.44	.433†	-1.30	-2.32	-0.28	**0.043*†**	-0.99	-2.01	0.04	0.376†
	limitfatigue	0.71	-0.55	1.97	0.27	-0.60	-1.89	0.70	0.367	-1.09	-2.38	0.21	0.099
QOL	total	-1.24	-2.38	-0.10	.267†	0.77	-0.40	1.94	0.593†	1.04	-0.13	2.21	0.344†
	function	-1.40	-0.45	0.17	.706†	-0.08	-0.28	0.12	0.779†	0.13	-0.08	0.33	0.415†
	appearance	-0.09	-0.56	0.38	0.711	0.05	-0.21	0.31	0.703	-0.07	-0.32	0.19	0.611
	symptoms	0.42	0.04	0.81	.067†	-0.16	-0.45	0.13	0.554†	-0.44	-0.72	-0.15	**0.035*†**
	emotions	0.21	-0.27	0.68	0.395	-0.15	-0.57	0.28	0.496	-0.18	-0.60	0.24	0.408
ROM	flexaff	1.89	-9.62	13.40	0.747	-5.50	-17.06	6.06	0.351	-7.45	-19.01	4.12	0.207
	flexnonaff	3.33	-7.18	13.84	0.534	-10.72	-24.68	3.25	0.133	-19.00	-32.96	-5.04	**0.008**

LDEX>10		Between Group Changes b-8											
	n=8	int-con wk 0				int-con wk 0-4				int-con wk 0-8			
Measure	Varlable	md	CI	CI	p	md	CI	CI	p	md	CI	CI	p
	introtaff	-2.08	-14.15	9.98	0.849†	7.01	-6.43	20.44	0.53†	6.86	-6.57	20.30	0.508†
	introtnonaff	5.19	-5.73	16.10	0.352	-8.67	-22.66	5.32	0.225	-6.15	-20.14	7.84	0.389
	extaff	-3.08	-11.23	5.07	0.458	-1.17	-9.77	7.43	0.789	-0.41	-9.01	8.19	0.926
	extnonaff	-2.12	-9.81	5.56	0.602†	-1.85	-10.57	6.87	0.800†	3.03	-5.69	11.76	0.748†
	abductaff	-4.04	-16.64	8.55	0.529	-1.49	-14.40	11.43	0.822	-5.43	-18.35	7.48	0.41
	abductnonaff	0.58	-11.07	12.22	0.923	-6.75	-20.67	6.17	0.342	-14.70	-28.62	-0.78	**0.039***
	extrotaff	-1.90	-11.62	7.83	0.702	-4.62	-14.32	5.07	0.35	-2.20	-11.89	7.50	0.657
	extrotnonaff	-1.95	-11.81	7.91	0.698	-0.83	-8.11	6.44	0.822	-2.35	-9.63	4.93	0.527
STRENGTH	gripaff	1.05	-4.24	6.34	0.696	2.19	-0.71	5.08	0.139	-0.91	-3.80	1.99	0.54
	gripnonaff	-1.64	-6.29	3.02	0.49	1.17	-0.98	3.31	0.286	1.58	-0.56	3.73	0.148
	flexaff	-2.32	-21.98	17.34	0.817	4.38	-9.02	17.79	0.522	-2.83	-16.24	10.57	0.679
	flexnonaff	0.24	-20.81	21.29	0.982	-2.38	-17.69	12.93	0.761	-5.54	-20.85	9.77	0.478
	extaff	-12.24	-32.98	8.51	0.248	9.53	-7.61	26.67	0.276	-0.59	-17.73	16.58	0.946
	extnonaff	-10.13	-29.68	9.41	0.31	6.94	-11.43	25.31	0.459	-8.94	-27.31	9.43	0.34
	abductaff	-9.19	-28.11	9.73	0.341	7.88	-4.78	20.53	0.223	5.08	-7.57	17.74	0.431
	abductnonaff	-11.87	-32.29	8.55	0.255	8.45	-7.17	24.07	0.289	8.16	-7.46	23.78	0.306
	horadaff	-2.36	-15.48	10.76	0.724	-0.97	-11.37	9.43	0.855	-1.88	-12.28	8.52	0.723
	horadnonaff	-0.77	-14.70	13.16	0.913	-2.34	-14.06	9.38	0.696	-7.40	-19.12	4.32	0.216
	pecmajaff	1.70	-13.34	16.74	0.824	1.65	-9.49	12.78	0.772	-2.16	-13.30	8.98	0.704
	pecmajnonaff	4.21	-11.12	19.54	0.59	-1.84	-11.29	7.61	0.703	-4.60	-14.05	4.85	0.34
	pecminaff	1.14	-3.12	5.40	.623†	-0.02	-4.76	4.73	0.836†	-0.98	-5.73	3.76	0.604†
	pecminnonaff	-1.22	-6.81	4.38	0.67	1.60	-5.37	8.57	0.653	-0.80	-7.77	6.17	0.822
	saaff	-1.59	-13.47	10.28	0.793	6.52	-3.95	16.98	0.222	0.94	-9.48	11.37	0.859
	sanonaff	-0.08	-10.96	10.79	.616†	2.59	-4.36	9.55	0.755†	-4.26	-11.06	2.53	0.318†
ACTIVITY	weekly	-3288.04	-2313.08	1656.99	0.746	59.25	-2286.84	2405.33	0.961	-11126.69	-3472.77	1219.40	0.347
	level	-0.01	-0.54	0.51	.966†	-0.08	-0.70	0.54	0.949†	-0.17	-0.79	0.45	0.556†
	daily	0.25	-1.75	2.25	0.805	0.81	-1.73	3.34	0.533	0.79	-1.75	3.32	0.543

†=non-parametric analysis
***=P<0.05**

LDEX>10				Within Group Changes b-8							
				wk 0-4				wk0-8			
Measure	Variable	Gp	n	md	CI	CI	p	md	CI	CI	p
BMI	bmi	con	3	0.27	-0.14	0.68	0.490†	0.34	-0.07	0.75	0.547†
		int	5	-0.34	-0.73	0.06	0.183†	-0.06	-0.46	0.33	0.801†
LYMPH	L-dex	con	3	-0.21	-2.37	1.96	0.85	1.17	-0.99	3.34	0.288
		int	5	1.67	-0.41	3.74	0.115	0.14	-1.93	2.21	0.893
	armvolume	con	3	-4.62	-33.46	24.22	0.754	0.86	-27.98	29.70	0.954
		int	5	-23.51	-49.84	2.82	0.08	-29.42	-55.75	-3.09	**0.029***
	handvolume	con	3	0.12	-2.06	2.30	0.914	-0.36	-2.54	1.82	0.746
		int	5	-2.43	-4.42	-0.45	**0.016***	0.06	-1.93	2.05	0.954
TON	forearmaff	con	3	1.89	-0.19	3.98	0.075	0.10	-1.98	2.19	0.923
		int	5	-0.20	-2.20	1.80	0.842	-1.76	-3.76	0.24	0.084
	forearmnonaff	con	3	0.41	-1.79	2.61	0.714	0.20	-2.00	2.40	0.858
		int	5	0.23	-1.87	2.34	0.828	-1.20	-3.31	0.90	0.262
	upperarmaff	con	3	2.11	-0.11	4.32	0.062	1.88	-0.33	4.09	0.096
		int	5	-0.05	-2.17	2.07	0.962	-1.33	-3.44	0.79	0.22
	upperarmnonaff	con	3	1.09	-0.99	3.16	0.305	1.92	-0.16	3.99	0.07
		int	5	0.09	-1.80	1.98	0.926	-0.97	-2.86	0.93	0.317
	chestaff	con	3	0.57	-1.00	2.14	0.476	-1.25	-2.82	0.31	0.117
		int	5	-0.42	-1.92	1.09	0.588	-1.61	-3.11	-0.11	**0.035***
	chestnonaff	con	3	1.04	-0.75	2.83	0.431†	-0.83	-2.62	0.96	0.103†
		int	5	0.20	-1.52	1.91	0.844†	-1.17	-2.88	0.54	0.309†
	upperbackaff	con	3	0.81	-1.93	3.54	0.563	0.59	-2.15	3.32	0.675
		int	5	1.84	-0.78	4.46	0.168	0.78	-1.84	3.40	0.56
	upperbacknonaff	con	3	1.19	-1.18	3.56	0.323	0.92	-1.45	3.28	0.449
		int	5	1.60	-0.66	3.87	0.166	-0.50	-2.77	1.77	0.665
VAS	sensations	con	3	0.70	-0.53	1.92	0.146†	0.04	-1.19	1.27	0.744†
		int	5	0.55	-0.63	1.73	0.522†	-0.51	-1.68	0.67	0.406†
	pain	con	3	-0.58	-1.14	-0.03	**0.04***	-0.26	-0.81	0.30	0.369
		int	5	0.08	-0.46	0.61	0.782	-0.19	-0.72	0.34	0.48
	fatigue	con	3	-0.18	-1.19	0.82	0.723	0.36	-0.65	1.36	0.489

LDEX>10				Within Group Changes b-8							
				wk 0-4				wk0-8			
Measure	Variable	Gp	n	md	CI	CI	p	md	CI	CI	p
		int	5	0.00	-0.96	0.96	1	-0.69	-1.65	0.27	0.159
	limitsensation	con	3	0.15	-0.88	1.17	0.78	-0.42	-1.44	0.60	0.422
		int	5	-1.11	-1.09	0.87	0.828	-0.60	-1.58	0.38	0.229
	limitpain	con	3	0.80	0.06	1.54	**0.037*†**	0.74	0.00	1.48	0.063†
		int	5	-0.50	-1.21	0.21	0.644†	-0.25	-0.96	0.46	0.220†
	limitfatigue	con	3	0.05	-0.89	0.98	0.924	0.65	-0.29	1.58	0.176
		int	5	-0.55	-1.44	0.34	0.228	-0.44	-1.34	0.45	0.333
QOL	total	con	3	-0.27	-1.12	0.57	0.397†	-0.45	-1.30	0.39	0.320†
		int	5	0.50	-0.31	1.31	0.880†	0.58	-0.23	1.39	0.692†
	function	con	3	-0.02	-0.16	0.13	0.612†	-0.19	-0.33	-0.05	0.593†
		int	5	-0.02	-0.16	0.13	0.985†	-0.19	-0.33	-0.05	0.165†
	appearance	con	3	0.00	-0.19	0.19	1	0.00	-0.19	185.00	0
		int	5	0.05	-0.13	0.23	0.581	-0.07	-0.24	0.11	0.462
	symptoms	con	3	0.01	-0.20	0.22	0.917†	0.13	-0.08	0.34	0.307†
		int	5	-0.15	-0.35	0.05	0.388†	-0.31	-0.51	-0.11	0.051†
	emotions	con	3	-0.08	-0.38	0.23	0.622	-0.10	-0.40	0.20	0.519
		int	5	-0.22	-0.51	0.07	0.134	-0.28	-0.57	0.01	0.062
ROM	flexaff	con	3	11.00	2.65	19.35	**0.01***	19.36	11.01	27.72	**0***
		int	5	5.50	-2.50	13.50	0.178	11.92	3.92	19.91	**0.003***
	flexnonaff	con	3	10.80	0.49	21.11	**0.04***	20.50	10.19	30.81	**0***
		int	5	0.08	-9.33	9.50	0.986	1.50	-7.91	10.91	0.755
	introtaff	con	3	0.91	-8.80	10.61	0.935†	5.64	-4.07	15.34	0.521†
		int	5	7.92	-1.38	17.21	0.231†	12.50	3.21	21.79	0.056†
	introtnonaff	con	3	8.50	-1.83	18.83	0.107	11.90	1.57	22.23	**0.024***
		int	5	-0.17	-9.60	9.26	0.972	5.75	-3.68	15.18	0.232
	extaff	con	3	4.09	-2.12	10.30	0.197	9.91	3.70	16.12	**0.002***
		int	5	2.92	-3.03	8.86	0.336	9.50	3.55	15.45	**0.002***
	extnonaff	con	3	5.60	-0.84	12.04	**0.043*†**	8.80	2.36	15.24	**0.006*†**
		int	5	3.75	-2.13	9.63	0.339†	11.83	5.95	17.71	**0.020*†**
	abductaff	con	3	1.82	-7.51	11.15	0.702	13.18	3.85	22.51	**0.006***

LDEX>10				Within Group Changes b-8							
				wk 0-4				wk0-8			
Measure	Variable	Gp	n	md	CI	CI	p	md	CI	CI	p
		int	5	0.33	-8.60	9.26	0.942	7.75	-1.18	16.68	0.089
	abductnonaff	con	3	1.50	-8.78	11.78	0.775	10.70	0.42	20.98	**0.041**
		int	5	-5.25	-14.64	4.14	0.273	-4.00	-13.39	5.39	0.404
	extrotaff	con	3	3.46	-3.55	10.46	0.334	5.36	-1.64	12.37	0.133
		int	5	-1.17	-7.87	5.54	0.733	3.17	-3.54	9.87	0.355
	extrotnonaff	con	3	0.00	-5.37	5.37	1	1.10	-4.27	6.47	0.688
		int	5	-0.83	-5.74	4.07	0.739	-1.25	-6.16	3.66	0.617
STRENGTH	gripaff	con	3	-1.23	-3.32	0.86	0.25	0.86	-1.23	2.96	0.418
		int	5	0.96	-1.04	2.96	0.348	-0.04	-2.04	1.96	0.967
	gripnonaff	con	3	-0.50	-2.08	1.08	0.536	-0.25	-1.83	1.33	0.757
		int	5	0.67	-0.78	2.11	0.366	1.33	-0.11	2.78	0.071
	sflexaff	con	3	1.82	-7.86	11.50	0.713	5.38	-4.30	15.06	0.276
		int	5	6.20	-3.07	15.47	0.19	2.55	-6.72	11.82	0.59
	sflexnonaff	con	3	11.78	0.70	22.86	**0.037***	10.74	-0.34	21.82	0.057
		int	5	9.40	-1.16	19.96	0.081	5.20	-5.36	15.76	0.335
	sextaff	con	3	-17.46	-29.83	-5.08	**0.006***	-10.93	-23.31	1.45	0.084
		int	5	-7.93	-19.78	3.93	0.19	-11.52	-23.37	0.34	0.057
	sextnonaff	con	3	-7.98	-21.27	5.31	0.239	-0.88	-14.17	12.41	0.897
		int	5	-1.04	-13.71	11.64	0.873	-9.82	-22.49	2.59	0.129
	sabductaff	con	3	5.49	-3.65	14.63	0.239	4.42	-4.72	13.56	0.343
		int	5	13.37	4.62	22.12	**0.003***	9.50	0.75	18.25	**0.033***
	sabductnonaff	con	3	8.24	-3.06	19.54	0.153	3.42	-7.88	14.72	0.553
		int	5	16.69	5.91	27.47	**0.002***	11.58	0.80	22.36	**0.035***
	shoradaff	con	3	6.20	-1.31	13.71	0.106	2.80	-4.71	10.31	0.465
		int	5	5.23	-1.96	12.43	0.154	0.92	-6.28	8.11	0.803
	shoradnonaff	con	3	10.14	1.66	18.62	**0.019***	4.20	-4.28	12.68	0.332
		int	5	7.80	-0.29	15.89	0.059	-3.20	-11.29	4.89	0.438
	specmajaff	con	3	0.56	-7.49	8.60	0.893	-0.59	-8.64	7.45	0.886
		int	5	2.20	-5.50	9.90	0.576	-2.75	-10.45	4.95	0.484
	specmajnonaff	con	3	4.40	-2.44	11.24	0.207	2.20	-4.64	9.04	0.528

LDEX>10				Within Group Changes b-8							
				wk 0-4				wk0-8			
Measure	Variable	Gp	n	md	CI	CI	p	md	CI	CI	p
		int	5	2.56	-3.96	9.08	0.441	-2.40	-8.92	4.12	0.471
	specminaff	con	3	2.40	-1.03	5.83	0.211†	3.00	-0.43	6.43	0.223†
		int	5	2.38	-0.90	5.66	0.319†	2.02	-1.26	5.30	0.369†
	specminnonaff	con	3	0.40	-4.53	5.33	0.874	1.80	-3.13	6.73	0.474
		int	5	2.00	-2.93	6.93	0.426	1.00	-3.93	5.93	0.691
	ssaaff	con	3	7.41	-0.75	15.56	0.075	8.39	0.29	16.50	**0.042***
		int	5	13.92	7.36	20.48	**0***	9.34	2.78	15.90	**0.005***
	ssanonaff	con	3	11.98	6.74	17.22	**0*†**	12.64	7.61	17.67	**0*†**
		int	5	14.58	10.01	19.14	**0*†**	8.38	3.81	12.94	**0.019*†**
ACTIVITY	weekly	con	3	-78.96	-1773.57	1615.66	0.927	166.23	-1528.39	1860.84	0.848
		int	5	-19.71	-1642.18	1602.76	0.981	-960.46	-2582.93	662.01	0.246
	level	con	3	0.00	-0.45	0.45	0.870†	0.09	-0.36	0.54	0.725†
		int	5	-0.08	-0.51	0.35	0.703†	-0.08	-0.51	0.35	0.703†
	daily	con	3	0.33	-1.51	2.16	0.726	-0.14	1.97	1.70	0.884
		int	5	1.13	-0.62	2.89	0.205	0.65	-1.10	2.40	0.468

†=non-parametric analysis
Bold=P<0.05
Lymph=lymphoedema
Ton=tonometry
VAS=visual analogue scale
QOL=quality of life
flex=flexion
introt=internal rotation
ext=extension
abduct=abduction
extrot=external rotation
horadd=horizontal adduction
pecmaj=pectoralis major
pecmin=pectoralis minor
sa=serratus anterior

LDEX>10						Between Group Changes 8b-12			
	n=8	int-con wk 8b				int-con wk 8b-12			
Measure	Variable	md	CI	CI	p	md	CI	CI	p
BMI	bmi	3.71	-0.67	8.09	0.064†	0.17	-0.32	0.65	0.843†
LYMPH	ldex	-12.04	-24.97	0.89	0.068	2.57	-0.85	5.99	0.14
	armvol	-112.45	-240.81	15.92	0.086	35.20	3.09	67.32	**0.032***
	handvol	2.00	-8.49	12.49	0.669†	-0.26	-3.14	2.63	0.853†
TON	forearmaff	1.42	-6.91	9.75	0.738	-0.43	-2.64	1.79	0.707
	forearmnonaff	-1.10	-12.33	10.13	0.847	0.10	-2.92	3.13	0.947
	upperarmaff	-5.39	-14.07	3.28	0.223	0.95	-1.27	3.17	0.402
	upperarmnonaff	-4.87	-14.00	4.26	0.296	0.53	-1.84	2.89	0.662
	chestaff	0.80	-7.05	8.65	0.842	-0.60	-2.81	1.61	0.593
	chestnonaff	3.94	-9.80	17.68	0.383†	-1.22	-5.10	2.67	0.688†
	backaff	-3.93	-13.65	5.79	0.428	1.10	-1.51	3.70	0.409
	backnonaff	1.09	-11.48	13.67	0.865	-0.48	-3.90	2.95	0.785
VAS	sensations	-1.12	-6.37	4.14	0.677	0.30	-1.13	1.73	0.681
	pain	-2.99	-7.05	1.08	0.15	0.81	-0.27	1.89	0.142
	fatigue	-1.16	-7.56	5.25	0.723	0.42	-1.35	2.20	0.64
	limitsensation	-1.05	-4.14	2.03	0.503	0.37	-0.44	1.17	0.373
	limitpain	-2.96	-8.12	2.19	0.26	0.72	-0.72	2.15	0.326
	limitfatigue	-2.28	-7.09	2.54	0.322†	0.61	-0.71	1.93	0.952†
QOL	qtotal	-1.43	-4.32	1.45	0.33	0.44	-0.34	1.22	0.264
	qfunction	-0.35	-1.08	0.38	0.344	0.13	-0.06	0.32	0.185
	qapp	-0.48	-1.75	0.79	0.46	0.10	-0.23	0.43	0.556
	qsymp	-0.51	-1.32	0.30	0.217	0.17	-0.04	0.38	0.104
	qemot	-0.27	-1.25	0.71	0.645†	0.04	-0.22	0.29	0.552†
ROM	flexaff	-3.47	-45.67	38.74	0.872	-1.37	-12.95	10.21	0.817
	flexnonaff	-33.11	-87.03	20.81	0.229	4.89	-10.20	19.98	0.525
	introtaff	38.94	13.65	64.23	**0.003***	-10.97	-17.03	-4.91	**0***
	introtnonaff	-5.22	-44.32	33.88	0.793	1.67	-9.06	12.39	0.761
	extaff	12.04	-11.47	35.56	0.315	-5.96	-12.28	0.37	0.065
	extnonaff	20.00	-4.16	44.16	0.105	-6.33	-12.87	0.20	0.058
	abductaff	2.87	-37.60	43.33	0.89	-4.90	-16.00	6.20	0.387
	abductnonaff	-7.44	-51.15	36.26	0.738	-3.00	-15.18	9.18	0.629
	extrotaff	7.02	-13.41	27.44	0.501	-4.20	-9.70	1.30	0.135
	extrotnonaff	-9.89	-28.53	8.75	0.298	0.89	-3.49	5.27	0.691
STRENGTH	gripaff	-11.07	-19.62	-2.52	**0.011***	3.58	1.61	5.56	**0***
	gripnonaff	-3.67	-12.04	4.71	0.391	0.83	-1.23	2.89	0.428
	flexaff	-5.84	-55.41	43.73	0.817	-0.56	-12.96	11.83	0.929
	flexnonaff	20.08	-29.15	69.30	0.424	-8.54	-20.54	3.47	0.163
	extaff	-7.31	-62.19	47.57	0.228†	-3.82	-18.07	10.44	0.278†
	extnonaff	-6.42	-59.03	46.20	0.811	-3.88	-17.16	9.39	0.566
	abductaff	-15.28	-56.55	25.99	0.468	2.89	-7.30	13.09	0.578
	abductnonaff	-4.17	-48.50	40.16	0.854	-1.22	-12.58	10.13	0.833
	horadaff	8.48	-25.24	42.19	0.622	-4.82	-13.80	4.17	0.294
	horadnonaff	15.78	-17.25	48.81	0.349	-8.59	-17.39	0.22	0.056
	pecmajaff	-1.96	-27.89	23.97	0.882	-0.02	-6.67	6.62	0.994

LDEX>10					Between Group Changes 8b-12			
	n=8	int-con wk 8b			int-con wk 8b-12			
Measure	Variable	md	CI	CI	p	md	CI	CI	p
	pecmajnonaff	35.82	8.15	63.48	**0.011***	-11.83	-18.79	-4.86	**0.001***
	pecminaff	-1.46	-12.40	9.48	0.794	0.44	-2.56	3.44	0.774
	pecminnonaff	-5.45	-27.71	-16.81	0.873†	1.53	-4.67	7.73	0.875†
	saaff	11.13	-25.45	47.70	0.551	-3.32	-13.34	6.69	0.515
	sanonaff	-8.31	-42.51	25.89	0.634	1.45	-7.90	10.80	0.761
ACTIVITY	ipaqtotal	-6,209.49	-11,706.09	-712.89	0.111†	1,383.50	-53.75	2,820.75	0.114†
	ipaqlevel	0.09	-1.53	1.71	0.913	-0.12	-0.56	0.31	0.583
	activity	1.39	-8.95	11.73	0.792	-0.43	-3.34	2.48	0.773

*=non-parametric analysis
Bold=P<0.05

LDEX>10				Within Group Changes 8b-12			
				wk 8b-12			
Measure	Variable		n	md	CI	CI	p
BMI	bmi	con	3	-0.023	-0.356	0.31	0.816†
		int	5	0.142	-0.208	0.493	0.920†
LYMPH	ldex	con	3	-0.86	-3.221	1.491	0.473
		int	5	1.711	-0.767	4.19	0.176
	armvol	con	3	-9.487	-32.194	13.219	0.413
		int	5	25.716	3.009	48.422	**0.026***
	handvol	con	3	0.222	-1.817	2.262	0.926†
		int	5	-0.033	-2.073	2.006	0.836†
TON	forearmaff	con	3	-1.193	-2.719	0.333	0.125
		int	5	-1.618	-3.226	-0.01	**0.049***
	forearmnonaff	con	3	-2.713	-4.793	-0.633	**0.011***
		int	5	-2.61	-4.803	-0.417	**0.02***
	upperarmaff	con	3	-3.156	-4.686	-1.626	**0***
		int	5	-2.207	-3.819	-0.594	**0.007***
	upperarmnonaff	con	3	-3.493	-5.163	-1.823	**0***
		int	5	-2.967	-4.636	-1.297	**0***
	chestaff	con	3	0.543	-0.976	2.062	0.484
		int	5	-0.059	-1.661	1.543	0.943
	chestnonaff	con	3	1.483	-1.191	4.157	0.469†
		int	5	0.268	-2.551	3.087	0.788†
	upperbackaff	con	3	-3.276	-5.066	-1.486	**0***
		int	5	-2.181	-4.068	-0.294	**0.023***
	upperbacknonaff	con	3	-0.607	-2.965	1.751	0.614
		int	5	-1.083	-3.569	1.403	0.393
VAS	sensations	con	3	0	-0.985	985	1
		int	5	0.3	-0.739	1.339	0.571
	pain	con	3	-0.41	-1.155	0.335	0.281
		int	5	0.4	-0.385	1.185	0.318
	fatigue	con	3	-0.69	-1.909	0.529	0.267
		int	5	-0.267	-1.552	1.019	0.684
	limitsensation	con	3	-0.2	-0.755	0.355	0.48
		int	5	0.167	-0.418	0.751	0.576
	limitpain	con	3	-0.53	-1.517	0.457	0.293

LDEX>10				Within Group Changes 8b-12			
				wk 8b-12			
Measure	Variable		n	md	CI	CI	p
		int	5	0.189	-0.852	1.23	0.722
	limitfatigue	con	3	-0.39	-1.296	0.516	0.980†
		int	5	0.222	-0.733	1.178	0.902†
QOL	qtotal 1-10	con	3	0	-0.536	0.536	1
		int	5	0.444	-0.121	1.01	0.123
	qfunction	con	3	0.037	-0.095	1.169	0.583
		int	5	0.167	0.028	0.306	**0.019***
	qappearance	con	3	0	-0.229	0.229	1
		int	5	0.1	-0.142	0.342	0.417
	qsymptoms	con	3	-0.169	-0.311	-0.027	0.02
		int	5	0.002	-0.147	0.152	0.977
	qemotions	con	3	-0.015	-0.192	0.162	0.912†
		int	5	0.02	-0.167	0.207	0.399†
ROM	flexaff	con	3	2.7	-5.27	10.67	0.507
		int	5	1.333	-7.068	9.735	0.756
	flexnonaff	con	3	1.111	-9.559	11.781	0.838
		int	5	6	-4.67	16.67	0.27
	introtaff	con	3	4.3	0.13	8.47	**0.043***
		int	5	-6.667	-11.062	-2.271	**0.003***
	introtnonaff	con	3	-4.111	-11.694	3.472	0.288
		int	5	-2.444	-10.028	5.139	0.528
	extaff	con	3	3.4	-0.952	7.752	0.126
		int	5	-2.556	-7.143	2.031	0.275
	extnonaff	con	3	3.889	-0.734	8.511	0.099
		int	5	-2.444	-7.067	2.178	0.3
	abductaff	con	3	3.9	-3.743	11.543	0.317
		int	5	-1	-9.056	7.056	0.808
	abductnonaff	con	3	4.778	-3.836	13.392	0.277
		int	5	1.778	-6.836	10.392	0.686
	extrotaff	con	3	2.2	-1.588	5.988	0.255
		int	5	-2	-5.993	1.993	0.326
	extrotnonaff	con	3	1.556	-1.541	4.652	0.325
		int	5	2.444	-0.652	5.541	0.122
STRENGTH	gripaff	con	3	-3.25	-4.607	-1.893	**0***
		int	5	0.333	-1.097	1.764	0.648
	gripnonaff	con	3	-0.333	-1.79	1.123	0.654
		int	5	0.5	-0.957	1.957	0.501
	sflexaff	con	3	3.06	-11.591	5.471	0.482
		int	5	-3.622	-12.614	5.37	0.43
	sflexnonaff	con	3	2.844	-5.402	11.091	0.499
		int	5	-5.692	-14.414	3.031	0.201
	sextaff	con	3	-3.54	-13.352	6.272	0.815†
		int	5	-7.356	-17.698	2.987	0.099†
	sextnonaff	con	3	1.044	-8.08	10.169	0.822
		int	5	-2.84	-12.483	6.803	0.564
	sabductaff	con	3	-6.76	-13.775	0.255	0.059

LDEX>10				Within Group Changes 8b-12 wk 8b-12			
Measure	**Variable**		**n**	**md**	**CI**	**CI**	**p**
		int	5	-3.867	-11.261	3.528	0.305
	sabductnonaff	con	3	-5.2	-13.006	2.606	0.192
		int	5	-6.424	-14.669	1.82	0.127
	shoradaff	con	3	-1.54	-7.726	4.646	0.626
		int	5	-6.356	-12.876	0.165	0.056
	shoradnonaff	con	3	2.911	-3.153	8.975	0.347
		int	5	-5.674	-12.061	0.714	0.082
	specmajaff	con	3	-2.42	-6.994	2.154	0.3
		int	5	-2.444	-7.266	2.377	0.32
	specmajnonaff	con	3	3.911	-0.878	8.7	0.109
		int	5	-7.915	-12.977	-2.854	**0.002***
	specminaff	con	3	-7.04	-9.106	-4.974	**0***
		int	5	-6.6	-8.777	-4.423	**0***
	specminnonaff	con	3	-7.04	-11.212	-2.868	**0.003*†**
		int	5	-5.51	-10.091	-0.928	**0.053*†**
	saaff	con	3	0.88	-6.011	7.771	0.802
		int	5	-2.444	-9.708	4.819	0.51
	sanonaff	con	3	-4.578	-11.028	1.873	0.164
		int	5	-3.128	-9.896	3.639	0.365
ACTIVITY	ipaq total	con	3	-752.7	-1741.906	236.456	.343†
		int	5	630.78	-411.911	1673.467	0.160†
	ipaq rate1-3	con	3	-0.1	-0.4	0.2	0.514
		int	5	-0.222	-0.539	0.094	0.169
	daily	con	3	0.94	-1.063	2.943	0.358
		int	5	0.511	-1.6	2.622	0.635

†=non-parametric analysis
***=P<0.05**
Lymph=lymphoedema
Ton=tonometry
VAS=visual analogue scale
QOL=quality of life
flex=flexion
introt=internal rotation
ext=extension
abduct=abduction
extrot=external rotation
horadd=horizontal adduction
pecmaj=pectoralis major
pecmin=pectoralis minor
sa=serratus anterior

APPENDIX F WOMEN'S JOURNEYS

Individual journeys H2: My journey towards self-knowledge

Acknowledging that this was the right moment to embark on a different journey with her lymphoedema ("I've been having conventional treatment for about 3 years now and it seems to have stabilised… it never seems to improve in any way at all...we seem to have arrived at a stalemate"), one participant quickly encountered the first hurdle to overcome-her immense dislike of evening activities: "Generally I retire with the 6 o'clock news and that's the last you'll see of me until the following morning."

A second concern was that she had never been a person inclined to become involved in yoga or anything of that nature: "I've just been very practical, very sceptic."

However, putting aside these two qualms, she was open-minded and enthusiastic enough to fully immerse herself in the trial, with the result that she was actually quite surprised over the 8 weeks how much she enjoyed the whole experience: "I looked forward to my DVD sessions which I found very relaxing, very calming, very balancing" and in so doing had 100% compliance rate. The yoga intervention also proved really useful (another source of surprise) and made a big difference to her general feeling of wellbeing.

The most dramatic change, however, occurred at the level of awareness. She had always just gone straight at things, everything was just expected to work, no thought had ever gone into it, but now "the yoga has made me very, very much more aware of how everything actually operates. And so, instead of just doing something, the exercises that we've been given, I actually have put some thought into what I'm doing and how I'm doing it, rather than just barging in with no thought at all. And that's been very, very interesting to me."

And, on the mental plane, another substantial change took place: "During the trial I've been fascinated because I never realised I had such a disorganised brain. I always thought I was a person who was able to focus and achieve, do things, but I've discovered I've got a brain that drifts off like a butterfly and it cannot be brought to focus for very long, with the attention-span of an ant, which is another interesting thing that I had never actually considered before. My brain has always got me pretty well where I wanted to go."

She has always taken so much for granted and now to suddenly realise that things could have been done a lot better or easier, the whole experience has been absolutely fascinating. Occasionally, she has what she calls "little epiphanies", when all of a sudden things will slot into place and she thinks: "Why is it such hard work all these years when you can just do this and this and it works?" And this is how it has been with this the yoga: "If I'd done this 30 or 40 years ago, when it was all the fashion, I might have learnt something which would have been very helpful to me all these years."

Her latest epiphany now puts yoga in a very positive light, so much so, in fact, that she believes subjects like this should be in the school curriculum: "Instead of always emphasising the ability to chase a ball or hit something hard, I think it would just be so much more valuable if young people were taught how their bodies work, where effort can be minimised by recognising the group of muscles which is going to achieve something, instead of just barging into it." Now a fervent believer in the mental and physical power of yoga, her journey will continue, she intends to keep "rowing" through the DVD and maybe even, for the second time in her life, put aside her 60-year conviction that the night air is poisonous and attend an evening class again.

Her objective scores resulted in improvement in QOL sub-scales of symptoms and emotions and ROM of the shoulder, as well as in improved posture (less pelvic obliquity and reduced angle of kyphosis) and way of moving in the spinal mobility tests. Her high QOL (9/10) and lack of pain, fatigue and sensations were maintained. Her lymphoedema level, did not alter. Once again, the interview brought out an additional improvement that was not measured elsewhere: "I was surprised how much I've enjoyed the whole experience and the big difference it's made to my general feeling of wellbeing."

Individual journeys H14MG: My Journey to holistic health

When an international athlete finds that a scientific project, in which she would dearly like to be involved ("being part of a study was something that I had always wanted to do"), is to be held at the same time as her training session, a difficult choice awaits: "At first, I said to Annette that I couldn't do it because my athletics was something I didn't want to have to forego, something that I was already passionate about." Then, realising that it would only be for a short time and that it would satisfy her long-held desire to be part of a research project, as well as helping herself and other women, she decided to enrol.

For her, the situation was very different from that of the L02. Having finished all her treatment only 12 months before, and newly diagnosed with lymphoedema, hers was a gradual journey of daily improvement, solidification and progression back towards health: "The yoga has contributed to an improvement in my general wellbeing, it's given me something else to help me on my journey, it's just solidified the progression." On a physical level, she is now experiencing less arm pain, does not have to wear her sleeve as frequently, has noticed improvements in her posture and core strength and overall, has a heightened awareness of her physical self, a great bonus for an elite athlete. The relaxation techniques have helped her to clear her mind and sleep better, to overcome the recent personal trauma of cancer and lymphoedema diagnosis and to deal with the current challenges of two young children, cancer, a busy job and "less than spectacular marriage". And, echoing what the majority of the participants claimed as being one of the most significant qualitative outcomes of the trial, she really appreciated and benefitted from the "Time for Self" period (both coming out to the weekly class and finding the daily 42 minutes).

Conscious of the considerable benefits brought about by her improved core strength and greater physical awareness, she will now strive to incorporate what she sees as useful stretching and other yoga movements into her athletics exercise regime. "It's definitely helped me on all levels. It's helped me physically, mentally, emotionally...a little bit on all levels, which is really nice and why I enjoy it." That initial "clash"–between yoga and athletics - has been successfully resolved.

The improvements she felt were quantified by her improvement in total QOL and in the sub-scales of symptoms and emotions and by a reduction in sensations, pain and all measures of fibrous tissue. ROM and strength of the shoulder and stabilising muscles of the shoulder also improved for various actions. The spinal mobility tests showed improved posture and way of moving. All of which, she felt, would make her running even better, now that "I am aware of all those things, physical and mental."

Individual journeys LO1: My second journey

For one participant, the opportunity to take part in medical research and the possibility of "maybe down the track being able to support or help somebody else" were too attractive to resist, even though it meant retracing parts of a journey that she had made 20 years earlier. That was the amount of time elapsed since her breast cancer treatment from which she had, in her own mind, moved on. It was also the amount of time that she had had lymphoedema.

Many questions had to be answered and issues re-thought, much soul-searching was necessary before she enrolled, but happily, she has no regrets and is totally convinced of yoga's physical benefits: more shoulder mobility, better posture, increased body awareness, better sleep, and new-found ability to open the garage door and hold her grandchildren.

The trial was also a profound experience for her on an emotional level: “I loved the yoga classes, I’ve been happy to share, instead of shutting myself off, as I did before, when I didn’t share with anybody. I told nobody. I continued to work. My boss knew. And so, I’d go to work in the morning and then I’d go and have my radiation treatment in the afternoon, go home, go to bed, get up and go to work in the morning.” How different were things this time! How much did she appreciate and enjoy sharing, talking, listening and learning among like-minded, trusting women! “Being part of that group of women was a really powerful experience for me.”

And on an even more personal note, her increased feelings of calmness and overall wellbeing, brought about particularly by the DVD relaxation, have helped her cope with her husband who has been suffering chronic depression for the last two years: a situation that she describes as “a huge benefit.”

Through all the experiences that she had to re-live, and all the memories that were evoked, “the yoga has been fabulous for me. I’m totally convinced that it’s worked for me.” She will continue this second journey, this wonderful experience, which has been totally different from the first one and which “has brought me emotional and physical benefits, in all areas of my life.”

Her observations were borne out by quantified improvements in lymphoedema status, QOL, degree of sensations, pain and fatigue, ROM of the shoulder and spine, strength of the shoulder stabilisers and posture.

Individual journeys LO2: Journey towards my former self

The most remarkable journey was made by a 65-year-old Italian immigrant who, prior to the trial, “was very, very depressed, very low, run-down”. Permanently tired, without energy, unable to pick herself up, she had to lie on the couch for an afternoon nap in order to get through the day. She had withdrawn from people, which only increased her depression because she had always loved being around them: friendly, talkative, sociable and helpful, isolating herself was completely against her nature. She was unable to talk to people about the things besetting her because she would cry all the time. Everything became a drama, the past, the present, little things were blown out of proportion. Relationships with her husband and children were affected “I was going through really tough times.” So, when she enrolled in the trial, it was with the firm intention of improving her mental and emotional state: “I have to go back to the person I used to be… Before, I think I didn’t really push myself to get better.”

An initial defining moment came in the very first week of the trial when she decided of her own accord to stop taking the anti-depressant medication prescribed by the family doctor. She wanted to take control of her life again and to give the yoga every chance to be effective. This, of course, required a considerable change: she had to leave home, to drive, to meet a new group of women in unfamiliar surroundings. Happily, her sociable self quickly returned. She found herself looking forward to the classes, where “mixing with other people with my problem was really good. We got to talk, to express ourselves, what we had done.” The yoga classes provided a calm, safe and trusting environment for everyone to share their ideas and experiences: “That aspect of sharing in what we had been through. That was really nice… Sharing the ideas is, I think, the best thing you can do.” She was happy to relate her story to the other women and valued listening to theirs. At last, she was talking, hearing and learning about the breast cancer and lymphoedema experience, which is precisely what she had been incapable of doing pre-trial. And, as it all took place in a very relaxed way, it was of immense benefit to her. Changes were also noticeable at home, where she had no trouble in getting and staying motivated for her daily DVD session. She really enjoyed having that time for herself, doing something for herself, looking after herself a bit more. She was no longer a victim of that immense fatigue; no longer did she need the afternoon naps: “To say that I was too tired would just have been lazy.”

So, how does this 65-year old immigrant see herself post-trial? What makes her claim that “I am a totally different person”? Psychologically and emotionally, the yoga has had a huge impact. Calmer,

more relaxed, more confident, she once again actively pursues her personal interests: “I look forward to doing things: go into the kitchen and start to cook a meal, do my beading, make my jewellery.” Procrastination is a thing of the past: “I know I have to do this and I’m not postponing anything, because that’s what I used to do. I have to do that and go for it. When I wasn’t well, I said to myself: “No, it can wait.” I’m a lot more motivated.”

Communication with her husband has improved immeasurably. Instead of being REACTIVE (interviewer’s word), “snappy” (her word), and ready to fight about any little thing he said to her, she remains calm, he behaves better and things are discussed in a more loving atmosphere . She also has a much better relationship with others as her true love of people has returned: “I want to get out, I am a lot more social now. My friend and I, we go for a walk, let’s do this, or she’ll give me a call or I’ll ring her up: ‘How’re you going? What are you doing?’” Keeping in touch with somebody makes all the difference because I can talk about things, not shutting myself away.” This is an extraordinary personal change in a woman who described herself as being depressed, withdrawn, unsociable and uncommunicative only a few months before.

An additional benefit of the yoga trial is that she sleeps a lot better: “When I finish my exercise, I go to bed and I sleep right through. Since I’m doing the exercise night-time, I don’t even have to get up to use the bathroom or anything. I just sleep right through till 6a.m.” And this, quite naturally, adds to her overall wellbeing and enjoyment of life.

Her energy levels are dramatically higher. Little by little she is becoming physically stronger, more flexible and mobile. She finds herself able to reach, stretch and bend further: “I can move my arm better. In terms of movement, it worked for me, it really worked for me. I’ve got more movement.” She is motivated to exercise more and accepts that even if she struggles, it is worth the effort: “I am pushing myself to do it and it’s doing me good, doing me a lot of good (p3)... I can move better. When I bend I can actually touch the floor now, which I haven’t been able to do for a long time.”

Three particularly exciting changes relate directly to her breast cancer treatment and lymphoedema. She no longer has the numbness in her arm that she had pre-trial. The scar on her breast is now much softer. And there has been a noticeable reduction in the amount of breast fluid being retained: “It is not swollen in the way it used to be.” For her, this is a big step on her journey, a wonderful outcome which she is confident in attributing to the yoga classes and her home-practice DVD.

All in all, the trial was an amazing experience for her, having a much greater impact on her life than she had expected: “I have made gradual but continuous progress over the two months, bringing me back to the woman I was. I don’t say 100% but I am almost 100%”. The yoga transformed her life, mentally, emotionally, physically. The journey towards her former self is almost complete.

Her scores for all aspects of QOL improved markedly (total QOL: “0” at baseline, “7” at week 8). Other objective improvements were in sensations and fatigue, spinal mobility, ROM of the shoulder and strength of the stabilising muscles of the shoulder girdle. Subjectively and objectively, her journey of returning to her former self was reflected in her words: “It (the yoga) really worked for me”.

Individual journeys LO8: Increasing my confidence

Though still very conscious of her breast cancer experiences, to which she made numerous references during the post-trial interview, one woman felt it was the right time of her life to try something different and that if it did not work, she would enjoy it anyway. As it turned out, it did work. The interaction in class removed a certain feeling of isolation and provided her with helpful information: “I never really joined a support group or anything because I just thought I was one of those people that didn’t really need to do that, but sometimes I wish I had because I’ve just realised through going to the classes how much better it makes me feel to know that other people go through the same things or similar things, and the different things they do.” Of equal importance, participation in the trial restored the control over her own life that breast cancer had taken away. The period when she having all the procedures and treatment was a pretty scary time, during which some big decisions

had to be made. Not knowing much about the things happening around her, and quickly realising that searching for information on the internet was simply adding to her fear because she did not really know what she was looking for anyway, she was obliged to put her trust in the professionals hoping that she had the best ones: “I did feel confident that everyone was definitely working for my best outcomes, but you just don’t understand a lot about it… you just feel like you’re in a boat that’s being buffeted around, and doing all these things, and hoping everything’s going to turn out alright.” Unable to say: “I don’t want to do this” or “I don’t want to come to that appointment today. I’d rather do something else”, she just felt that the whole thing had taken charge of her life, a feeling that increased her introversion, anxiety and stress.

The yoga trial was something that she chose to do herself, to help herself, without anyone saying: “This is what you should do.” It was her decision; she was back in control of her life, a major development whose benefits have flowed into other areas of her life. More optimistic, positive, confident and relaxed, less worried about everything to do with breast cancer, she now feels capable of doing what she wants to do, without having to worry that something might happen: “It’s just made me think more outwardly and stop me focusing so much… because I think for a couple of years you just worry about every little medical thing and every little aspect of your body that’s affected by all this. I feel like it’s just taken that away from me.” Now, she just goes with the moment.

She is also much more at ease with her self-image. Though it was never a really big issue, the fact that her underarm is slightly convoluted where the lymph nodes were taken out, used to worry her a little: “That’s not very attractive and I won’t be able to wear sleeveless tops any more. And I won’t be able to go swimming any more.” Now, however, it no longer concerns her: “Everyone is so different anyway, who cares? Why would anyone be looking at my underarm anyway? It has made me feel a bit more confident in that respect.”

Her QOL scores remained fairly even but were not low at baseline. So, in her case, the interview gave valuable information about her improved mental awareness that was not obvious in the objective QOL questionnaire. Physically and mentally, she had become more confident.

ATTACHMENT 1 THE HOME-PRACTICE DVD